

## Annual reports from the Committees

53<sup>rd</sup> Meeting of the Management Board 28-29 March 2019

### Key messages

#### RAC and SEAC

Members achieved the required level of contribution to the work of the Committees during 2018. RAC noted a much larger number of CLP dossiers (62 adopted against a 5 year average of 35). RAC also adopted three opinions on Occupational Exposure Limits in 2018, based on proposals drafted by ECHA, successfully adding a new process to ECHA's work.

- The MB is requested to note the increasing workload of RAC and SEAC in 2019 2020 and the efficiency measures being implemented by the agency to manage this.
- The MB is requested to consider additional resources for RAC, specifically in the form of **advisors to current members** who could take their place or accompany them in the new **RAC AfA working group** from **September 2019 to September 2020**. The required experience is: environmental and workplace exposure assessment/risk management measures.
- The MB is requested to consider additional resources for SEAC, specifically in **increasing the membership** back to the 2015 level and to **appoint advisors to current members** who can accompany them in plenary and support their work as rapporteurs for restrictions and AfA. The required experience is: socio-economic analysis, analysis of alternatives and substitution of SVHCs.
- 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. In 2018, ECHA recommended to the MB that a dialogue with ECHA and the Chairmen as to the suitability of members prior to their (re-)appointment was needed. The further support of the MB in this regard would be appreciated, as this remains problematic.

#### MSC

- The Management Board is invited to take note of the specifics and functioning of MSC.
- The Management Board is invited to comment on MSC's workload drivers and support for a joint ECHA/MSCA planning of SEV and SVHC cases, to further increase transparency and predictability of MSC workload, would be appreciated.

#### BPC

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

## Background

Previously, the Committees reported occasionally to the MB, e.g. in 2013, 2014 and 2017. The MB requested an annual report from the Committees, in particular RAC and SEAC – this has been placed on the March agenda each year and this is the second year of regular reporting.

Thus, in March 2018, the Management Board was invited to consider the proposed qualifications and process improvements to be applied to the (re-)nominations of RAC and SEAC members.

## 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.

Estimates of the contribution of members (and their advisors) were made from a) individual interviews with the whole membership by the Chairmen of RAC and SEAC held between October 2018 and January 2019 and b) the views of the secretariat, in particular with respect to commenting, between meetings, during written RAC and SEAC consultation rounds. These estimates also include the use of some advisors to members.

### RAC

As the table below shows, the proportion of members achieving a 50% or more contribution in RAC is in balance with those achieving less, the latter usually but not exclusively from smaller MS. The lower contribution groups also contains several new members whose work is still building up. The 5 members with a greater than 80% contribution (usually with the help of advisors) make a strong contribution to RAC's work.

Member's % time contribution	Number
<20	6 (12.5%)
20-50	19 (39.6%)
50-80	18 (37.5%)
>80%	5 (10.4%)

### SEAC

For SEAC, the estimates are less quantitative but roughly one third of members contributing ca. 50%, one third contribute more and one third contribute much less. With two instead of four processes to deal with in SEAC, contribution in terms of time is not the issue for most members but more the level of experience and competence with socio-economic analysis and assessment of alternatives, leading in practical terms to about one third of the members carrying out most of the work.

### Rapporteurships in RAC and SEAC in 2018

The number of rapporteurships for dossiers adopted in the years 2015 to 2018 can be seen in figure 1 below. For RAC, a decline in the need for AfA rapporteurships from 2017 is more than made up for by an increase in CLP rapporteurships in 2018.

**Table 1.** SEAC and RAC members' rapporteurships<sup>1</sup> 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				<b>106</b>	<b>43</b>
2016	2	3	113	107	57				<b>172</b>	<b>110</b>
2017	8	6	105	104	52	8		8	<b>181</b>	<b>110</b>
2018	6	6	42	44	107	9	1		<b>164</b>	<b>50</b>

For RAC, the number of rapporteurships needed annually is increasing with increased numbers of Restrictions, CLP, in particular Afa and now OEL's. For SEAC, the picture is less stable, as the Afa peaks have a greater impact.

### Numbers, turnover of members, renewals and new nominations

MSCAs continue to appoint/renew members largely without reference to ECHA and sometimes without adequate arrangements with the nominee's employer to secure their time. ECHA realises that the process of nominating members can be complex and can occur at a high political level in some MS. Nonetheless, a proper dialogue as to the suitability of members is needed prior to their appointment. Both Committee's needs in terms of expertise vary from year to year and finding suitably qualified members with a proven track record and competence is critical to the effective functioning of RAC and SEAC.

#### RAC

RAC had a total of 47, 49, 50 and 52 EU/EEA members in December of 2015, 2016, 2017 and 2018 respectively; almost from the start of the Committee growth has been linear but has now reached a break point.

Seven members have indicated that they do not wish to be renewed in 2019 or that their MSCA's have other plans. This number includes two members impacted by the withdrawal of the UK from the EU. Usually an average of 3 to 4 members per year are replaced; on this occasion the number is higher and there are indications that many may not be replaced immediately.

#### SEAC

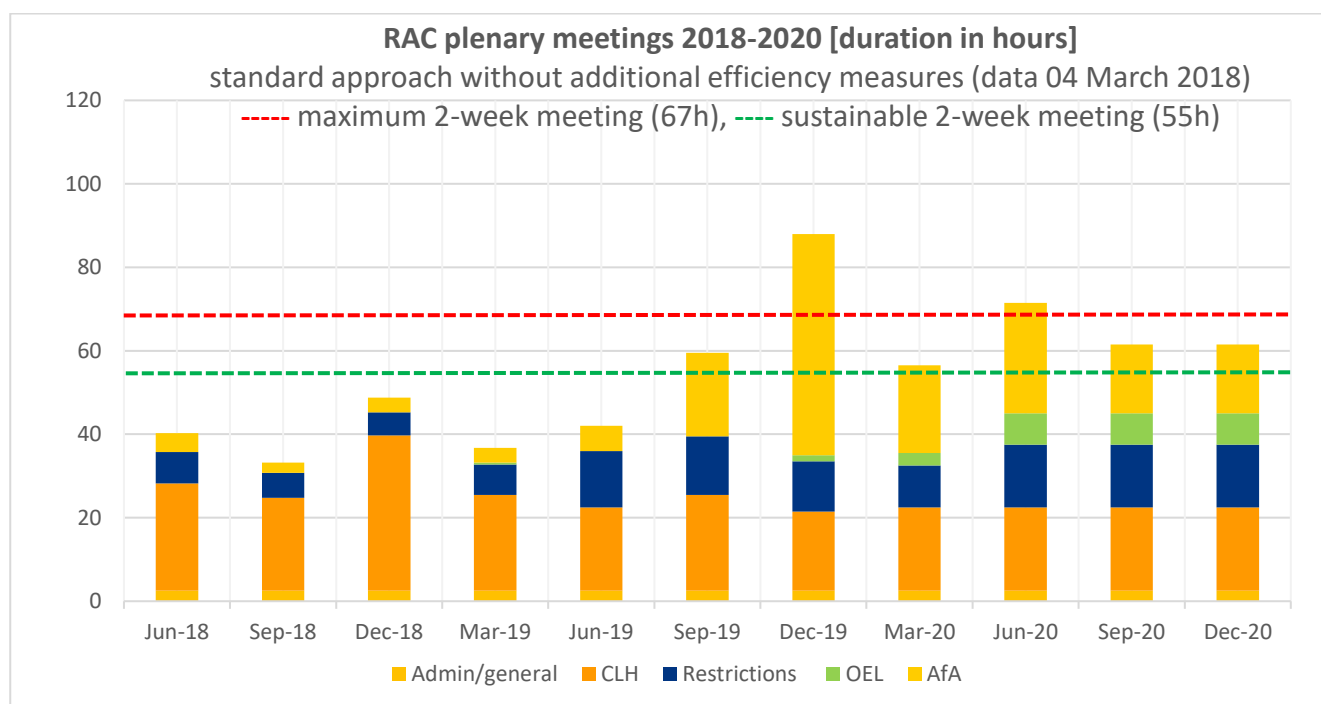
SEAC had a total of 40, 39, 35 and 34 EU/EEA members in December of 2015, 2016, 2017 and 2018 respectively; here the trend is declining and gives a different cause for concern. SEAC's expected turnover of members also includes two members impacted by the withdrawal of the UK from the EU.

### Prognosis and workload management.

Looking ahead to 2019 and 2020, the workload projections for RAC and SEAC are challenging to say the least, with a continued higher number of CLP dossiers (ca. 50) and the start of OELs on a permanent basis in RAC, Restrictions (10, against an annual average of 2-3) and a large increase in Afa in the second half of 2019 (an expected 120 opinions with 95% certainty) in RAC and SEAC expected.

<sup>1</sup> 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.

The graph below shows estimated plenary time in RAC through 2019 and 2020. A series of efficiency and planning measures (see next section), will be implemented to smooth out the peak and bring meetings back to below 2 weeks in duration. For reference, a full 2 week meeting (red line) contains 67 debating hours; while a sustainable meeting length is <55h in duration (green line).



### Further efficiency measures

A series of related efficiency measures are planned:

- Setting up a working group of RAC to prepare Applications for Authorisation to a large extent outside of plenary - SEAC will shorten the debating time for individual dossiers and expand to double meetings as needed without a working group;
- 'A-listing' of simpler AfA opinions (as already done with CLP), i.e. with scrutiny of the members but without plenary debate;
- Lowering of the quorum in both Committees to handle longer meetings more effectively (the subject of a separate paper to the MB);
- An overall policy of much shorter, more readable opinions will be introduced into all RAC and SEAC processes, in particular AfA but also for restrictions and CLP, e.g. through amended templates, page limits, executive summaries etc. Less reliance on presentations in plenary will also be considered.

### AfA working group of RAC

To address the next AfA peak and at the same time, make provision for future peaks, ECHA will set up an AfA working group of RAC - initially on a pilot basis - to pre-evaluate mainly downstream AfA opinions for groups of similar opinions. This is broadly in line with what was agreed at the COM-ECHA workshop on AfA in November 2018. In this way, AfA opinions will be handled as much as possible outside of the RAC plenary but with the required level of scrutiny. The WG will meet between RAC meetings as part of a revised opinion development schedule.

The WG will be set up as foreseen in the REACH regulation and the RAC Rules of Procedure, thus applying similar conditions of participation. It will be populated by RAC rapporteurs for AfA dossiers, their advisors, co-opted members and strongly supported by ECHA staff.

## PART II

### MSC

#### Background

The Member State Committee (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 which would prevent an adequate discussion on the topics addressed by MSC.

MSC conducts its business based on scientific and technical arguments which MSC members assess and implement in the REACH regulatory setting. Some Member States have significant scientific resources dedicated to support their MSC members, whereas other members have to rely upon ECHA's and the other members' experts, and thus focus on the proper assessment and implementation of the regulatory process. In dossier and substance evaluation most proposals for amendment are submitted by a small group of 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.

The MSC involvement is triggered when proposals for amendment (PfA) - Art. 51(4) for dossier and substance evaluation cases - or comments on the hazard profile of a substance - Art. 59(7) for SVHC identification cases- are received. These triggers are only available to MSC a few weeks before the meeting (7 weeks in case of PfAs and 3 weeks in case of SVHC comments) which currently makes the MSC workload difficult to accurately predict on a longer time-frame.

#### Main achievements and challenges



- 100% unanimous agreements
- 90 agreement and opinions
- 5 plenary meetings
- 11 written procedures
- High member interest and commitment

MSC reached **unanimous agreements on all of the SEV, DEV and SVHC cases<sup>2</sup>** in 2018, within the legal deadline (of 60 or 30 days after referral to MSC). Number-wise this is:

<u>Process</u>	<u>Agreed cases</u>	<u>Agreed in WP</u>	<u>Agreed in MTG</u>
DEv- TPE	13	8	5
DEv - CCH	45	25	20
SEV	19	7	12
SVHC	12	4	8
<i>Sum</i>	<i>89</i>	<i>44</i>	<i>45</i>

MSC also issued its opinion on draft CoRAP, so actually this sums up to **90 agreements and opinions**.

In order to achieve this, MSC held **5 plenary meetings** (MTG) (total duration of 13 full days, spread over 15 calendar days). This also required **11 written procedures** (WP) for agreement seeking or decision making prior to the meeting, and also 9 preparatory WebEx meetings were

<sup>2</sup> 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.

organised to which whole MSC was invited to prior to the plenaries. Also two working groups and rapporteurs contributed to the work, and held smaller meetings and WebExes during the year. The first MSC-RAC workshop was held in October.

The members continue to show **interest and commitment** to their tasks as shown in the very high participation to both the plenaries (av. >26 in a meeting out of 29) and to the written procedures.

MSC's main challenge remains a constantly high and unpredictable workload.

## Dossier evaluation

For the dossier evaluation process the Chairman shares with the members, shortly after the PfA

- Less meeting time needed for case presentations
- More quality time per issue at the meeting
- Transparency of written procedure cases improved for Stakeholders

submission, his assessment whether resolution of the PfA has to be sought after a discussion in the meeting, or whether further discussion is not required since the PfA can be considered resolved. MSC members can comment on this assessment, and if all PfAs on a case are considered resolved the case is submitted for formal agreement seeking in written procedure. Cases with one or more unresolved PfAs are for the meeting, where only the unresolved PfAs are introduced and discussed. This measure allowed MSC to spend more quality time on resolving the remaining divergences. Another factor that has contributed to the many successful MSC outcomes, is also the informal interactions with MSC members and MSCAs one on one, the WebExes, and the early morning and late

evening discussion groups before and after the plenary meeting. In addition, for the MSC regular stakeholder observers' transparency on the reasoning for submitting cases to written procedure has been further improved through the introduction of a briefing breakfast with the Chairman on the first day of the meeting.

ECHA and Member States are faced by a call to increase the percentage of dossiers being checked for compliance. This will result in an increased number of cases that are to be notified to MSCAs: From 300 substances to be assessed per year for registrations over 100 tonnes to more than 600 for registrations below 100 tonnes; moreover, it is estimated that on average 8 decisions per substance assessed will be sent to joint submission members. This will have a knock-on effect on MSC's workload by end of 2019/early 2020, if the current rate of Proposals for Amendments (PfAs) is sustained. ECHA and Commission are developing a Joint Action Plan<sup>3</sup> where a number of actions for improving efficiency are introduced that includes improving a.o. the text of the decisions to be clearer, more concise and easier to defend and enforce. This action is expected to reduce the need for PfAs from the Member States, hereby decreasing the number of procedural steps of adopting a decision and decreasing workload for Member States, ECHA and the registrants. Considering that in 2018, 35% of all CCH and 16% of TPE (and 100% of SEv cases) received PfAs and that, on average, a PfA on a draft decision leads to doubling the workload of the Secretariat compared to the case where no PfA is received, this action should bring efficiency gains and lead to quicker data generation.

In addition, 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 increase efficiencies, but also to ensure consistency. While the PfA step in the process is a welcome quality control, it is however expected that the vast majority of scenarios have already arisen through the past compliance checks and a common understanding within the MSC has been reached regarding the action

<sup>3</sup> See agenda point B.4a - Update on dossier evaluation work – MB/05/2019

needed. Therefore, ECHA and MSCAs should consider more efficient ways to identify and resolve diverging scientific views in dossier and substance evaluation.

## Substance evaluation and SVHC identification

In 2018, MSC identified several priority actions to improve the transparency and efficiency of its work. For substance evaluation the MSC working procedures were reviewed and one change

- ECHA staff to support and guide more the MSCA scientific experts
- MSCA experts to engage early on with their Member State MSC member

recently introduced is that the evaluating MSCA proposes to MSC whether they consider a PFA resolved and do not require an introduction or discussion in the plenary meeting. Similarly, for SVHC identification the MS Dossier Submitter suggests to MSC that some of the comments received in public consultation do not require further introduction and discussion at the meeting. These initiatives already have resulted in a reduced time requirement for their presentations, but since this was introduced at the end of 2018 it is too early to

assess the impact on the number of meeting days required.

ECHA staff are well placed, due to their long-time experience with the regulatory and legal aspects of the REACH decision making process, to support and guide the MSCA scientific experts who are responsible for the preparation and initial drafting of substance evaluation decisions and SVHC Annex XIV dossiers. Early interaction to identify the legal hurdles and define the strategy jointly in complex cases can reduce the number of PfAs, or comments submitted, and thereby increase the overall efficiency of the decision making process. Additionally, if a MSCA scientific expert also engages in a close coordination and collaboration with their Member State MSC member significant learnings from previous cases discussed at MSC are even more readily transferred. Early incorporation in a draft decision of the latest MSC and Board of Appeal learnings will reduce MSC's need to introduce these aspects late in the decision making stage. Significant redrafting of SEv decisions or SVHC support documents with many actors involved during the MSC decision making stage is not necessarily an efficient use of everyone's time, and the tight legal deadlines may also have a negative impact on the final quality of the document. When MSC reaches a common understanding on the principles and key aspects of a decision or agreement then implementation in the final text, after the meeting and without undue delay, might be delegated to ECHA and the eMSCA or MS Dossier Submitter. ECHA and MSCAs may consider whether they see this approach as a feasible way forward, or if other measures to improve overall efficiency and quality are preferred.

## Other aspects

For the MSC opinion on the draft ECHA recommendation for inclusion of priority substances in Annex XIV, MSC has closely reviewed with ECHA the opinion forming process and the opinion format. This is now applied by the Rapporteur and Working Group for the development of the MSC opinion on the 9<sup>th</sup> draft ECHA recommendation. In contrast to RAC and SEAC, MSC appoints

- RECOM opinion format revised
- MSC to review its approach to identification of Rapporteurs

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 17 MSC opinions in total. It continues to be challenging and time consuming for the MSC Secretariat and Chairman to find a volunteer from the MSC membership. MSC will have to start considering whether and how to identify Rapporteurs

more efficiently than through volunteering.



MSC and RAC held, for the first time, a joint workshop to raise awareness regarding the possibilities and limitations each of the two committees is faced with and, where possible, to align views on three topical issues. The workshop achieved the overall objectives and the joint

[REDACTED]

- First MSC-RAC workshop a success

search for solutions and future ways of operating proved to be beneficial<sup>4</sup>. The feedback received was positive and future workshops on general topics of interest for different ECHA committees can be considered.

In the early years of MSC, the first meeting following summer was scheduled early-mid September, however, these meetings failed to attract submissions by evaluating MSCAs for possible substance evaluation decision making. For two years in a row now MSC has piloted to

[REDACTED]

- Joint planning of SEv and SVHC identification cases to further increase transparency and predictability of the MSC workload

hold its first meeting after summer in October. The pilot was aimed at increasing the number of substance evaluation decisions, but unfortunately did not achieve the expected result. Instead, based on the number of cases notified, the eMSCA preferred meetings for substance evaluation seem to be June and December which also cover the SVHC identification process. These two meetings therefore likely remain highly packed. Due to the unclarity in the timelines of the individual eMSCAs or Dossier

Submitters as well as whether the MSC triggers in REACH are met (i.e. Art. 51(4) or Art. 59(7)) the workload for MSC remains highly unpredictable until approximately 7-weeks before the meeting when the PfAs with ECHA's or eMSCA's responses become available to the members. ECHA, together with MSCAs, should consider if there are other ways to increase transparency in their planning and thereby increase predictability of the workload for MSC.

## 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 BG are represented in the BPC. In addition, CH and NO are represented in the BPC. In 2018, DK, EL, ES, MT and NO have appointed both a new member and an alternate member to the BPC.

For the Working Groups the number of core and flexible members is similar to 2017 with in total 33 core and 278 flexible members<sup>5</sup>. In 2018, there were no WG-members from MT and LU. Due to the large number of experts, the turnover of flexible members is relatively high. The WG-members are nominated until further notice.

### Performance 2018

The BPC adopted:

- 25 opinions on an application for approval of an active substance of which 7 contained a proposal for non-approval. In addition, 13 opinions were agreed at the BPC where the evaluating Competent Authority (eCA) now has to perform an assessment of the

<sup>4</sup> <https://echa.europa.eu/about-us/who-we-are/member-state-committee/meetings-of-the-member-state-committee/other-meetings>

<sup>5</sup> There are 8 core members in the Efficacy Working Group (WG) representing HR, FR, DE, EL, NL, RO, SI and UK; 5 alternate members representing FR, DE, EL, NL and UK and 63 flexible members. The Analytical methods and Physico-chemical Properties WG is composed of 7 core members representing FR, DE, EL, NL, PO, SI and UK; 3 alternate members representing FR, EL and NL and 43 flexible members. In the Human Health WG, there are 11 core members representing CZ, FR, DE, EL, IE, NL and UK; 4 alternate members representing DE, EL, NL and UK and 87 flexible members. The Environment WG includes 7 core members representing FR, DE, EL, IE, NL and UK; 6 alternate members representing DE, IE, NL and UK and 85 flexible members.



- endocrine disrupting (ED) properties after which the opinion can be adopted.
- 4 opinions on an application for Union authorisation, all for iodine containing biocidal product families used for teat disinfection of milk producing animals.
- 2 opinions on other processes: one on a disagreement in a mutual recognition process (Article 38) and one Article 75(1)(g) opinion requested by the Commission.

### Prognosis and workload management

Looking ahead to 2019 and 2020 the two main processes show a different development:

- For active substance approval the submission of draft evaluations by the eCAs to ECHA for peer review has almost come to a complete standstill. This results in a significant decrease in workload: the scheduled discussions for 2019 is currently 15; one meeting in 2019 has been cancelled. Main cause is most likely the assessment of ED properties.
- For Union authorisation the workload is – as expected – increasing. For 2019 it is foreseen that 17 opinions are adopted.
- In conclusion, the overall workload for the BPC and the Working Groups is manageable for 2019.

### 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 has become increasingly difficult to schedule the meeting agendas for the BPC due to the unpredictability of incoming draft evaluations by eCAs. 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.
- It is worrying that only a limited number of members comment for the Union authorisation process on draft BPC opinions, SPCs and PARs. In this respect the SECR is especially concerned about the quality of the SPC. 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 SECR is exploring the involvement of the Forum sub-group on the BPR with respect to advice on the enforceability of risk management measures. This has been discussed at the last BPC.
- With respect to the work of the Working Groups vis-à-vis the BPC the SECR – referring also to the workshop mentioned above – realises the need for increased efficiency and effectiveness, especially in the active substance approval process. It is noted that often the timeline of 270 days for a BPC opinion is not realised due to the need for more discussions at Working Group level, sometimes in the form of so-called ad-hoc follow-ups. Reducing complexity and more pragmatism may be key here to come to a more predictable and streamlined peer review process. The SECR realises this is a joint responsibility but asks the MB members to pay attention to this.

The progress of the Review Programme has been discussed in a dedicated workshop organised by ECHA in February. Here also several possibilities for improvement of the peer review process in the Working Groups and the BPC have been suggested, which will be discussed in the CA meetings of March and May. MB members are asked to contribute to the implementation of these improvements.

### Drawbacks

N/A

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