

Annual report from the Committees 2022

69th Meeting of the Management Board 30 March 2023

Key messages

RAC and SEAC

- The number of members in RAC has dropped again, from 45 in 2021 to 42 at the time of writing (down 10 from 2018). In the view of the Agency, in order to adopt ca. 100 opinions per year, the Committee's sustainable capacity is 50 regular and five co-opted members. This matter urgently requires the attention of the Member States (MS).
- The situation is similar for SEAC, where currently there are 31 EU/EEA members, down from 40 in 2015.
- Member State Competent Authorities (MSCA) are requested to provide further resources to increase the RAC membership to a minimum of 50 and SEAC to a minimum of 40 members, by encouraging their MS to appoint members to meet the expected number of rapporteurships in 2023-2024. Management Board members are also invited to raise this issue in their MS and to drive home the importance of having these committees fully resourced by experts from each MS
- The RAC and SEAC workload is expected to grow significantly in 2023-2024.
- RAC and SEAC held three in-person meetings in 2022, after 2 years of fully remote meetings. This resulted in a visible improvement in social cohesion and the integration of new members.
- ECHA notes with appreciation the recent nominations from 12 EU/EEA Member States to a new standing working group of RAC on the Drinking Water Directive and its EU Positive List.

MSC

- Due to its strong cohesion, commitment, and cooperation, MSC successfully solved all its divergences of opinion meeting cases unanimously. Furthermore, it agreed on the listing of seven substances of very high concern (SVHCs), including the heavily debated Melamine. MSC cases agreed in written procedure keep rising, reducing ECHA's and Member States' workload.
- MSC agreed on several general approaches for Evaluation, contributing to reducing ECHA's workload and the need for Proposals for Amendment (PfAs) coming from MSCAs.
- In support of the group assessment of bisphenols and ongoing work at RAC, MSC agreed on the endocrine properties of two bisphenols and its salts for the environment, at the request of the Executive Director.

BPC

- The predictability of the submissions by MSCAs of evaluations for peer review remains low. ECHA will continue to consult with MSCAs in 2023 to get more insight into their planning.

Background

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

PART I RAC and SEAC

Members' 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. RAC members reported that with decreasing membership, their contribution was closer to 70-80% in many cases, and that has been the case as well for several SEAC members, who declined to take on rapporteurships in the second half of the year, as they had already exceeded their allotted time. The Chairs of RAC and SEAC consider that the target of 50% was well met on aggregate in 2022 across the membership.

Opinions adopted in RAC and SEAC in 2022

Table 1. Opinions adopted in SEAC and RAC during 2008-2022. Including co-opted members from December 2015.

	SEAC				RAC					
	AfAs	Rest	Art 77(3)c	Total	AfAs	Rest	CLH	OEL	Art 77(3)c	Total
2008	0	0	0	0	0	0	0	0	0	0
2009	0	0	0	0	0	0	1	0	0	1
2010	0	0	0	0	0	0	16	0	1	17
2011	0	4	0	4	0	4	32	0	2	38
2012	0	1	0	1	0	2	31	0	1	34
2013	1	2	0	3	1	2	34	0	3	40
2014	30	4	0	34	30	5	51	0	2	88
2015	25	6	0	31	25	5	38	0	0	68
2016	63	2	0	65	63	2	35	0	1	101
2017	58	2	0	60	58	2	33	0	4	97
2018	26	4	1	31	26	4	61	0	5	96
2019	14	3	0	17	14	3	51	0	1	69
2020	96	7	1	104	96	7	50	2	4	159
2021	47	2	12	61	47	2	54	2	3	108
2022	36	4	0	40	36	4	41	4	2	87
TOTAL				451						1 003

The number of AfA opinions adopted reflects the peaks in Authorisation evaluations in 2017-2018, 2019-2020 and a new peak, which has started in the second half of 2022, with many additional opinions expected as a result in 2023. In SEAC, the total number of opinions tends to follow the numbers for AfAs, while in RAC, the numbers of CLH opinions also have a significant impact. The number of CLH opinions in 2022 was lower than normal at 41, but offset in terms of effort by the glyphosate and silver dossiers which are some of the largest we have seen.

It's important to note that the scale of a single dossier can vary by a factor of 50, i.e. from a few days to half a person per year. In general, restriction rapporteurships occupy members for a longer period, and they take up a higher proportion of the time they have available for the Committees. Larger and more complex restrictions (more common in recent years) also require

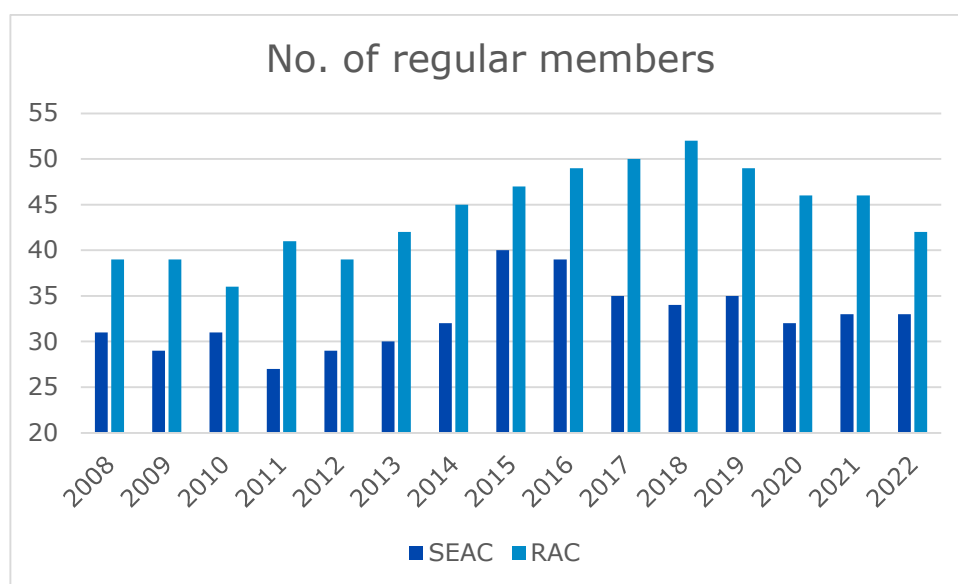
the formation of support groups amongst RAC and SEAC members, to aid the rapporteurs in their job. This occupies members beyond what is visible on the table. Thus, using the adopted opinions as a measure of output needs careful interpretation. It is, however, more meaningful than the number of rapporteurships, as previously presented.

Numbers, turnover of members, renewals and new nominations

ECHA appreciates being consulted by the MSCAs prior to nominating members, in order for the Chairs to inform on the skills needed and the type of candidate being sought. Proposed nominations which do not involve an appropriate level of support to the member (see Art. 85(7)) are advised against by the secretariat.

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 to achieve consensus on the opinions of RAC and SEAC.



RAC

As the graph above shows, membership in RAC is concerningly low, at 42 regular members at the time of writing, down from 45 in 2021 and from 52 in 2018. Competent rapporteurs are essential to RAC's output, and this urgently needs the attention of the Member States.

We note with sadness the untimely passing of two of our RAC friends and colleagues, Prof. Dr. Ralf Stahlman and Dr. Tom Gebel, in January 2023.

SEAC

SEAC currently has a total of 31 EU/EEA members, and the trend has been in decline since 2015. The chart above shows the numbers of members since that year. Efforts are being made with MSs to increase the membership, and some results were already seen in 2022 (including 2 new members nominated for appointment at this MB meeting).

The return to in-person meetings (RAC and SEAC had three in-person meetings in 2022, after 2 years of fully remote meetings) proved very valuable in ensuring the full integration of new members and improving social cohesion.

Prognosis and workload management

Looking ahead to 2022 and 2023, the workload projections for RAC and SEAC continue to be challenging. As reflected in the ambition of the Restriction roadmap, a higher number of Restrictions will continue to be in the system (7 to 8), against a previous annual average of 2-3 before 2019). In addition, the scope of many recent restrictions of groups of substances is much larger, requiring teams of members rather than just the rapporteurs to work on developing opinions. They can also result in longer opinion-making through 5 or 6 meetings in RAC and SEAC respectively, so that Rapporteurs are tied up with a single case for a longer period of time. For applications for authorisation, the next peak, including chromates is expected this year.

Remuneration

The Chairs of RAC and SEAC identified inconsistencies in the level and type of remuneration of members and rapporteurs and brought this to the attention of the MB. We appreciate the MB's decision on the improved remuneration of co-opted members.

However, the chairs see the inconsistencies with remuneration of all members acting as rapporteurs as a major obstacle to filling rapporteurships, particularly in Restrictions, where the maximum ceiling is far too low but also extending to other processes. The two members co-opted to RAC in 2021 especially for restrictions have both informed that they will not take on any further restriction dossiers due to the large disparity between remuneration on offer and the substantial number of days of work required. The lack of any remuneration for rapporteurships under CLH has also been identified as an issue that needs addressing.

Drinking Water Directive

In December 2022, ECHA sent an invitation to all EU/EEA member States to nominate experts to a new standing working group of RAC, intended to support the evaluation of substances for inclusion/removal from the EU positive list. We have received nominations from 12 EU/EEA Member States; this is greatly appreciated. As the expertise of this group of nominations is sufficient to commence the work of preparing for the start of evaluations in 2025-2026, ECHA is now in a position to call an inaugural meeting for the first week of June 2023.

The Chair of the RAC will leave ECHA in the second half of 2023. Measures are put in place to ensure a smooth hand-over.

PART II - MSC

Numbers, turnover of members, renewals and new nominations

MSC held three plenary meetings (two in ECHA premises and one virtually) to deal with its four MSC-decision-making rounds and other tasks in 2022. In February 2022 MSC managed to reach agreement on all its cases in written procedures and therefore that meeting could be cancelled.

At the well-received informal MSC Webex meeting to address developments in the Chemicals Strategy for Sustainability (CSS), MSC discussed subjects relevant for MSC work, i.e., considerations for REACH revision related to SVHC identification and prioritisation to Annex XIV, dossier and substance evaluation processes, and improvements of data requirements, including New Approach Methodologies (NAMs). A brief report was made available to participants and MSC

Stakeholders.

In 2022, MSC had 26¹ voting members with their 24 alternate members at the end of the year. All MSCAs were represented via either the member or alternate member or both. Additionally, NO was represented by its member and alternate member. In 2022 SK and NO appointed a new member to the MSC. In addition, a new alternate member was appointed for HR, FR, MT, and SE, and for a further 5 MSC members and 1 alternate member their mandates were renewed.

Main achievements and challenges

Decisions at MSC

MSC only discusses difficult cases where no agreement can be reached after consulting the member states (MSCAs) at its meetings. MSC reached unanimous agreements on all of these Dossier Evaluation (DEv), Substance evaluation (SEv) and Substance of Very High Concern (SVHC) cases² in 2022 within the legal deadlines of 60 days and 30 days after referral to MSC.

Table: overall MSC cases in 2022

<u>Process</u>	<u>Referred cases</u>	<u>Agreed cases</u>	<u>Agreed in written procedure</u>	<u>Agreed in Meeting</u>	<u>Referred to Commission</u>
DEv	20	20	18	2	0
SEv	5	5	3	2	0
SVHC	7	7	6	1	0
<i>Sum</i>		32	27	5	0

Efficiency gains in Dossier evaluation cases:

Figure 1 provides some further insight in the efficiency developed also at MSC on DEv over the years, notably reflected here 2017 – 2022. Although the number of DEv cases notified to MSCAs over the years increased, the cases referred to MSC decreased significantly. This is the result of a number of efficiency gains put in place in the DEv/MSCA and DEv/MSC interaction, such as:

¹ pending appointment from BG

² 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;

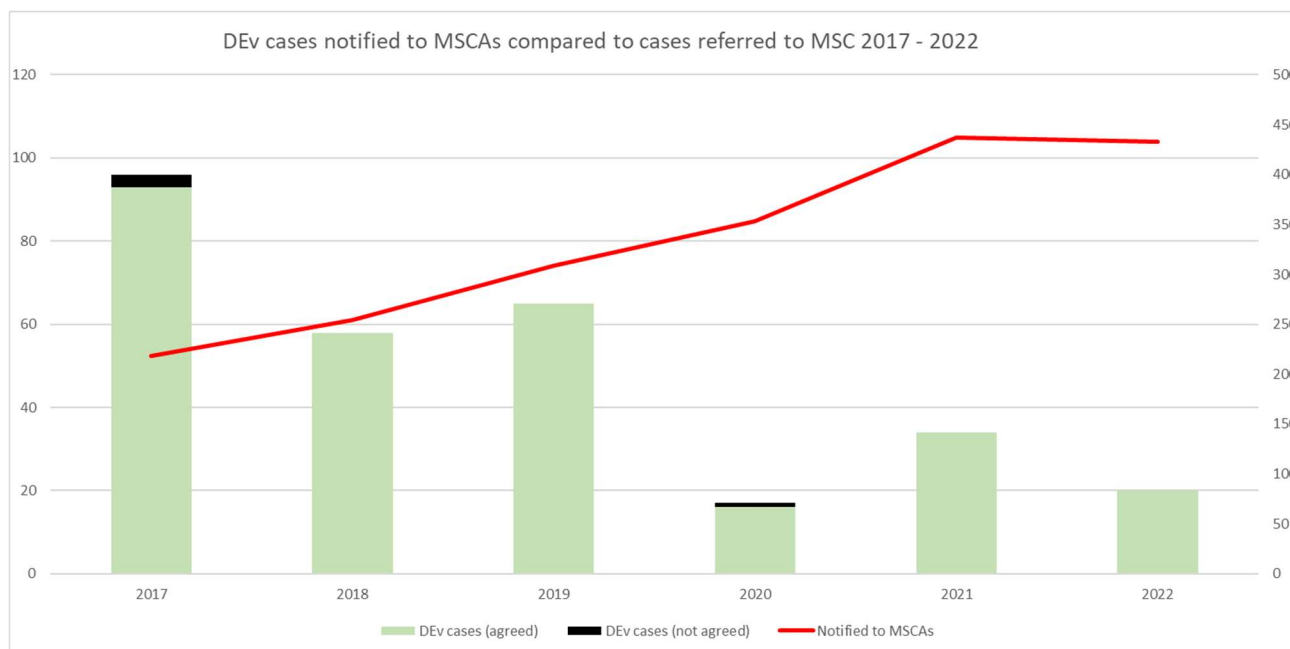


Figure 1: DEv process and MSC agreement 2017-2022 trend

a) *MSC discussed and agreed on general topics:*

MSC concluded in 2022 on its discussion on specific mutagenicity testing (chromosome aberration) under REACH. MSC agreed on a general approach consolidating the test requested in ECHA decisions to ensure optimal data collection *in vitro*. Also, with the same objective, the general approach for *in vivo* mutagenicity testing strategy (CA) was consolidated.

b) *Possibility to clarify issues before submission of PfAs:*

During MSCA consultation the Secretariat offers to clarify rationales applied in the draft decisions bilaterally, leading to a reduced need to submit PfAs and involvement of MSC in the decision-making.

To increase the output of DEv Draft Decisions (DDs) ECHA arranged one extra consultation in 2022 (MSC-78bis). These consultations do not need synchronization with an MSC meeting and MSC involvement was not triggered this time.

Efficiency gains in Substance evaluation cases:

Five SEv draft decisions prepared by MSCAs were referred to MSC for decision-making in 2022. Only two cases needed discussion at a plenary meeting, all others were agreed in written procedure (60%).

The average number of PfAs submitted per SEv case decreased to 3 in 2022, compared to 13 in 2018 and 2019. Furthermore, the proportion of cases not receiving PfAs significantly increased in 2022 to 44%, compared 14% in 2021.

The above outcomes were the result of a number of efficiency gains in the SEv/MSCA and SEv/MSC interaction, such as:

- Implementation of a revised draft decision template to improve the overall structure and clarity of draft decisions.
- Learnings and agreed MSC approaches from previous SEv cases were applied to new cases to ensure a consistent approach to cases with similar information requests.

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- Use of the Interact Collaboration tool for PfA consultation. This enabled more efficient review of the draft decisions for consideration of potential PfAs, including easier access to other PfAs submitted (to avoid duplicate submission of the same proposed amendments) and an option to indicate agreement/disagreement of a proposed amendment during the consultation period.
- Early interaction and negotiations led by the evaluating MS, in collaboration with the SEv team, after PfA submission.

Also, affected registrants were informed that their scope of the commenting should not go beyond what was proposed in submitted MSCA PfAs. Out of Scope comments are in principle not addressed at MSC.

SVHC identification:

In 2022, out of ten submitted SVHC proposals seven were referred to MSC for agreement. Under this task MSC unanimously agreed on the SVHC identification of for example two substances as endocrine disruptors for human health and/or environment, two as PMT under Art. 57(f) and four as PBT/vPvB or PBT. Some of the substances were identified as SVHC for more than one concern. 86% of the SVHC cases were agreed by MSC in written procedure, without further discussion at a meeting indicative of the strong cohesion and capacity built over the years in MSC, enabling a highly efficient decision-making process.

Opinions at MSC

Community Rolling Action Plan

In 2022, MSC adopted two opinions by consensus with no minority views – a) opinion on draft Community Rolling Action Plan (CoRAP) update for 2022-2024 and b) opinion on the endocrine disrupting properties of bisphenol F, bisphenol AF and eight bisphenol AF salts.

In support of work going on Bisphenols in RAC, at the request of the ECHA's Executive Director in accordance with Art. 77(3)c, MSC adopted by consensus an opinion on endocrine disrupting properties of bisphenol F, bisphenol AF and eight bisphenol AF salts. According to the opinion, drafted by a rapporteur and a co-rapporteur assigned by MSC, the substances meet the ED criteria. The MSC opinion will be considered in the context of restriction proposal for bisphenol A and other bisphenols with Endocrine Disrupting properties for environment at the RAC.

Another opinion (on ECHA's draft 11th recommendation for inclusion of priority substances in Annex XIV) remained in a drafting stage with the adoption expected early 2023.

In these processes five Rapporteurs and co-rapporteurs contributed to the work and held some smaller meetings preparing for MSC draft opinions.

At its December meeting (MSC-80) MSC thanked Charmaine Ajao, who provided support in her capacity as MSC deputy chair until the June MSC-78 meeting, for all her valuable contributions to MSC over the years.

Other aspects

Forward looking

Anticipating future changes, an informal training was provided to the MSC in 2022 on New Approach Methodologies (NAMs).

MSC was introduced to the legal requirements for nanoforms and ECHA's strategy for them in 2022 and the February MSC meeting of 2023 agreed unanimously on the first Annex VI compliance check decisions on substances containing nanoforms.

Figure 2 below shows that the fraction of cases agreed in written procedure for the many different processes dealt with at MSC has steadily increased over the years, with notably also the number of cases being brought to MSC reducing due to the co-development of generic approaches. To retain these efficiency gains it is vital that MSC as a Committee is able to retain its strong cohesion, members commitment and effective cooperation, as well as its competences.

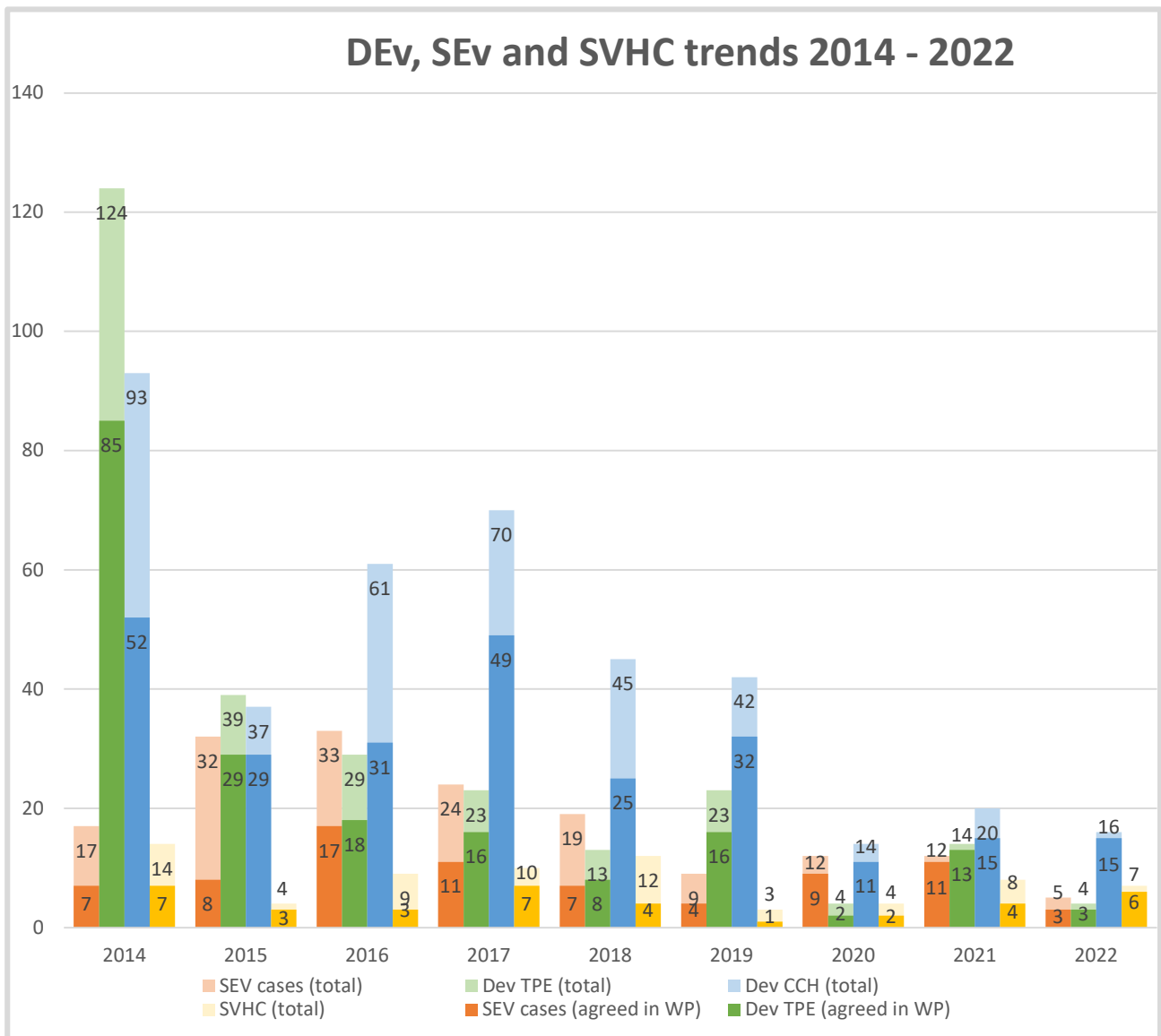


Figure 2: DEv, SEv and SVHC trends 2014-2022 trend

PART III - BPC

Numbers, turnover of members, renewals and new nominations

The number of BPC members is 28 where 27 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 2022 most of the members three-year term of office was due to expire, hence the membership renewal exercise was executed for 15 countries. This resulted in the nomination of one new member (DE) and two new alternate members (FI and HR). In addition, later during the year IE nominated a new member and alternate and NL a new member.

For the Working Groups the number of core members has decreased slightly in 2022 with a total of 32 core members. The number of flexible members has slightly increased compared to 2021 with a total of 288 flexible members³. In 2022, there were no WG members from BG, LT, LU, MT and PT. Due to the large number of experts, the turnover of flexible members is relatively high. The WG members are nominated until further notice.

Four BPC and four Working Group meetings were organised in 2022. All meetings were virtual, except the WG-II-2022 in June and BPC-45 in November which were organised as hybrid meetings, most of the members physically attending in Helsinki. These were the first hybrid meetings after the virtual meetings during the pandemic time. In general, the physical presence of members contributed positively to the quality of the discussions and is considered of utmost importance for the social coherence of the BPC and its Working Groups.

The Working Groups saw a major change in the secretariat staff in 2022 as for two of the permanent Working Groups (APCP and ENV), both the chair and deputy chair changed as a consequence of colleagues leaving. This required extra efforts in running the Working Groups by the secretariat including a hand-over exercise.

Performance 2022

The total opinions adopted by the BPC increased from 39 in 2021 to 57 in 2022.

The BPC adopted:

- 18 opinions (the same number as for 2021) on an application for approval of an active substance of which 12 for the Review Programme. For 2 opinions a non-approval was proposed: Methylene dithiocyanate in product type (PT) 12 and Mecetronium ethyl sulphate (MES) in PT 1;
- One opinion following an Article 15 request from the Commission related to an early review of iodine and PVP iodine due to ED concerns. It was concluded that these active substances meet the ED criteria;
- 22 opinions (compared to 15 in 2021) on an application for Union authorisation where for all opinions the BPC proposed to grant the authorisation⁴;

³ There are 6 core members in the Efficacy Working Group (WG) representing FR, DE, EL, NL, RO and SI; 4 alternate members representing FR, DE, EL and NL and 73 flexible members. The Analytical methods and Physico-Chemical Properties WG is composed of 6 core members representing FR, DE, EL, NL, PL and SI; 5 alternate members representing FR, DE, EL and NL and 49 flexible members. In the Human Health WG, there are 11 core members representing AT, CZ, FR, DE, EL, IE, NL and SI; 7 alternate members representing FR, DE, EL, IE, NL and SI and 90 flexible members. The Environment WG includes 9 core members representing AT, FR, DE, EL, IE, NL and SI; 6 alternate members representing FR, DE, EL and NL as well as 76 flexible members. The total number of flexible members is 288.

⁴ It is noted that the 'actual' proposal for authorisation may differ from the authorisation applied for by an

- two opinions following an Article 38 request from the Commission related to a dispute in a mutual recognition process for a biocidal product, where in both cases the BPC was able to solve the dispute by coming to a consensus agreement;
- 11 opinions following an Article 75(1)(g) request from the Commission: i) assessment of the ED properties of MBO and HPT (for in total 9 product types (PT) leading to 9 opinions); ii) analysis of alternatives for the active substance hexaflumuron in PT 18; iii) comparative assessment of anticoagulant rodenticides.
- Two opinions on post-authorisation conditions included in an adopted opinion for Union authorisation: In both cases the existing Union authorisation did not need to be amended.

In addition, the BPC agreed on a guidance document developed by ECHA on the analysis of alternatives in the frame of the active substance approval process. Also several procedural documents related to active substance approval and Union authorisation were agreed upon.

The activities of the Working Groups in the opinion-forming process remained stable in 2022 compared to 2021. A number of evaluating Competent Authorities used early WG discussions (7 in total) to receive guidance on their assessment. This has in particular been used for the assessment of endocrine disrupting properties and for environmental exposure assessments. The early WG discussions are facilitating the opinion-forming process as issues are solved up-front instead of during this process. The Working Groups addressed also many guidance related issues, such as: i) several new emission scenarios; ii) several revisions of existing scenarios (PT 11, PT 18, PT 19); iii) agreement of waiving requirements for physico-chemical hazards; iv) the PT11 and 12 updated efficacy draft guidance entered the ECHA consultation phase; v) work on a new draft guidance on resistance has started; vi) the updated efficacy guidance on disinfectants was published, vii) discussions on recommendations for in situ generated active substances and biocidal products; vi) discussions on the guidance for the risk assessment of pollinators.

Prognosis and workload management

Looking ahead to 2023 the following developments can be highlighted:

Processes:

- For active substance approval (first approval and renewal) based on the planning of submissions of assessment reports provided by the MSCAs, it is foreseen that the number of opinions will be similar: the number of opinions will probably be 19 or less (compared to 18 in 2022).
- For Union authorisation, based on the planning of submissions of product assessment reports provided by the MSCAs, it is foreseen that the number of opinions will decrease: the number of opinions will probably be 17 or less (compared to 22 in 2022).
- Probably three opinions on an Article 75(1)(g) request will be adopted in 2023: i) one related to the analysis of alternatives for MBO and HPT for 9 PTs; ii) one related to another question in the framework of the comparative assessment at EU level for anticoagulant rodenticides; iii) one on a remaining question considering the environmental risk assessment of ADBAC/BKC for PT 2. In addition, three opinions on an Article 38 request are expected to be adopted.
- In conclusion, the overall workload for the BPC and the Working Groups will decrease and is – related to the opinion-forming process - expected to be manageable for 2023 for the secretariat and the members. It is foreseen that the total number of opinions adopted will be lower compared to 2022: 42 or less versus 57.

applicant: sometimes restrictions are proposed or certain uses within an application are proposed not to be authorised.

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- The foreseen increase in workload for 2023 (especially with respect to Union authorisation comparable to what was observed in the previous years with an increasing trend each year) is not expected to materialise. The ECHA forecasts are based on the planning of submissions of evaluations received by ECHA from the MSCAs. The predictability of the submissions by MSCAs of evaluations for the opinion-forming process remains low. ECHA will continue to be in contact with MSCAs in 2023 to get more insight in their planning.

Guidance:

- Efficacy – in 2023 it is planned to discuss further at the EFF WG the antimicrobial resistance draft;
- Environment – in the frame of the Chesar Platform development, adjustments of the current guidance Volume IV Part B are triggered, which have been discussed with the ENV WG in 2022 and which will be further worked on in 2023. In addition, an emission scenario repository covering all existing emission scenarios including updates is under preparation;
- The finalisation of the revision of the recommendations of in situ generated active substances is targeted for the second half of 2023.

The Chair of the BPC will be replaced in the second half of 2023. Measures are put in place to ensure a smooth hand-over.

For questions: peter.vanderzandt@echa.europa.eu (RAC, SEAC, BPC),
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