

Interinstitutional files: 2025/0207 (COD)

**Brussels, 02 September 2025** 

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#### **INFORMATION**

From: To:	General Secretariat of the Council Ad hoc Working Party on the ECHA Basic Regulation
Subject:	ECHA Basic Regulation: Follow-up to WPE on 1 September 2025: Commission's presentation

Delegations will find attached the Commission slides presented at the AHWP ECHA meeting of 1 September 2025.

# Further explanations on Proposal for ECHA Basic Regulation

1 September 2025 DG GROW F.1

Council Ad Hoc Working Party on ECHA Basic Regulation





#### **General Comments**



#### Typos

- Article 9(1)(m) typo
- Article 14(15), the cross-reference should be to paragraph 12 (not 13)
- Article 15(4), the SCCS should be included in the list of committees whose rules of procedure require approval of the representatives of the Commission in the Management Board
- Article 16(5): cross-references should read 'The provisions on independence in Article 14(910), on contractual arrangements in Article 14(1314) and on the financial arrangements for remuneration in Article 14(1415) shall apply mutatis mutandis to any expert...'
- Article 19(3): space missing ('Article 14(10)with ')



#### **Typos**

- in the Annex I of the proposal:
  - point 15, the date '19 December 2024' is missing from the title
  - point 16, the indication '(recast)' is missing at the end of the title
  - In the footnote of point 20, the text should read 'please insert in the text the number of the **Directive'** (instead of Regulation),
  - point 24, the date ('30') is missing from 'Regulation (EC) No 1223/2009 of the European Parliament and of the Council **of November** 2009 on cosmetic products'.
  - point 24, the indication '(recast)' is missing at the end of the title.



#### **General Comments**

- Potential impact of the REACH revision on ECHA's workload and whether this has been taken into account in the proposal for the ECHA Regulation (reference to comment on p. 84 as part of the LFDS)
- on page 10 of the Explanatory Memorandum:
  - The Commission envisages an evaluation of current and potential new income streams particularly those related to services delivered by the Agency to undertakings having commercial activities.
  - This evaluation should take into account the changes stemming from the REACH revision



#### General comments – ECHA Headcount

- Elaboration on the changes in staffing within ECHA compared to the current headcount
  - See background slides on current and future situation of headcount
    - Based on <u>ECHA's Single Programming Document 2025-2027</u>
  - All legislative proposals assigning tasks to ECHA were accompanied with a Legislative Financial and Digital Statement (LFDS), only exceptions
    - CLP: resources covered by redeployment of existing resources within ECHA under the allocation for REACH
    - Toys: to be covered by existing resources
       (Reference: page 82, section 1.5.5. of the LFDS)
  - Resource needs of ECHA assessed in the context of the 1S1A Staff Working Document (<u>SWD(2023)850 final</u>))



#### 1. A snapshot of the situation of ECHA staffing (TA, CA, SNE / legislation or action) before and after implementation of the CSS actions

Staff popul	ation	Staff population in voted EU budget 2020					Staff population envisaged in 2027					Evolution 2020-2027				
		REAC H/ CLP	Bioci des	Environm ental Policy	Oth er tas ks	TOT AL	REAC H/ CLP	Bioci des	Environm ental Policy	Oth er tas ks	TOT AL	REAC H/ CLP	Bioci des	Environm ental Policy	Oth er tas ks	TOT AL
Offici	AD	-	-	-		-	-	-	-		-	-	-	-		-
als	AST	-	-	-		-	-	-	-		-	-	-	-		-
	AD	310	43	1		354	310	43	39		392	0	0	38	0	38
TA	AST	94	9	6		109	94	9	6		109	0	0	0	0	0
	AST/ SC															
Total AD+A	ST	404	52	7		463	404	52	45		501	0	0	38		38
Total (FTE)		102	15	2	11	130	97	15	28	15. 5	155 .5	-5	0	26	4.5	25. 5
SNE		13	2	0		15	3	2			5	-10	0	0	0	-10
Total		519	69	9	11	608	504	69	73	15. 5	661 .5	-15	0	64	4.5	53. 5

The projection for 2027 under Environmental Policy is without prejudice to the updates that may become necessary due to the ongoing legislative procedures and any resulting changes in the legislative-financial fiches.



#### 3. ECHA Resources per activity as at present

	2025			2026			2027			2028		
WP activity		CA/ SNE	Budget	TA	CA/ SNE	Budget	TA	CA/ SNE	Budget	TA	CA/ SNE	Budget
1. REACH/CLP	265	57	76 987 232	265	57	86 216 561	265	57	89 414 102	265	57	90 526 865
1.1 Dossier preparation	17	7	5 879 712	17	7	5 945 970	17	7	6 166 490	17	7	6 243 232
1.2 Dossier submission and processing	19	17	11 504 671	19	17	13 378 432	19	17	13 874 602	19	17	14 047 272
1.3 Identification and prioritisation of (groups of) substances	36	4	10 046 669	36	4	11 891 939	36	4	12 332 980	36	4	12 486 464
1.4 Evaluation	82	10	18 515 992	82	10	19 324 402	82	10	20 041 092	82	10	20 290 504
1.5 Authorisation	26	4	6 240 745	26	4	7 432 462	26	4	7 708 112	26	4	7 804 040
1.6 Restrictions	26	5	6 427 136	26	5	7 432 462	26	5	7 708 112	26	5	7 804 040
1.7 Classification and labelling	27	5	6 077 028	27	5	7 432 462	27	5	7 708 112	27	5	7 804 040
1.8 Data management	18	3	7 425 402	18	3	8 918 955	18	3	9 249 735	18	3	9 364 848
1.9 Making data publicly available	7	2	2 985 136	7	2	2 972 985	7	2	3 083 245	7	2	3 121 616
1.10 Promotion of alternatives to animal testing	7	0	1 884 740	7	0	1 486 492	7	0	1 541 622	7	0	1 560 808
2. Biocides	44	11	12 363 134	44	11	13 378 432	44	11	13 874 602	44	11	14 047 272
3. Environmental policy <sup>1</sup>	17	8	5 426 534	37	22	16 636 420	37	22	18 639 390	37	22	18 965 590
4. Other tasks, including tasks under grant, cooperation and service-level agreements	12	8.5	1 304 712	12	8.5	784 712	12	8.5	784 712	12	8.5	784 712
5. Governance and enablers	138	60	38 987 181	142	63	44 994 830	142	63	46 908 151	142	63	47 508 554
Overall TOTAL	476	144.5	135 068 793	500	161.5	149 433 955	500	161.5	154 946 957	500	161.5	156 865 513

Source: ECHA SPD 2025-2027

<sup>1</sup> The planned resources for 2025 do not include the following posts which are subject to adoption of the legislative proposals: Water Framework, Groundwater and Environmental Quality Standards (EQS) Directives - 7 TAs and 4 CAs; One Substance, One Assessment package 12 TAs and 8 CAs, in total €4,195,881. To indicate the potential growth in Environmental policy tasks, the figures for the period 2026 and onwards include the additional resources for these tasks.



#### Round one

Chapter I: General Provisions (Articles 1-4)

Chapter II: Organisation of the Agency (Articles 5-26)



## Chapter I: General Provisions (Articles 1-4)



#### Article 3 – Seat

• A reference to possible local offices, which could be established pursuant to Articles 56(2) and 12(7) has not been included in the proposal for Article 3 on the seat of the Agency to avoid confusion, also on the status of the local office.



#### Article 4(1) – Objectives and tasks – 'safe use'

- On para 1: Safe use (also referred to in recitals 9, 16 and 28)
  - not a new concept introduced into the ECHA Regulation
  - used in different pieces of chemicals legislation within ECHA's mandate:
    - Article 77(2),119 and 123 of REACH
    - Article 34 of CLP Regulation
    - Article 64 of BPR
    - Article 46(7) of the proposal for the Toys Regulation
  - not a new task for ECHA. What constitutes 'safe use' in a specific case, depends on the applicable legislation within which the assessment takes place and parameters and conditions set by the same.



#### Article 4 – Objectives and tasks

Provisions on the prevention of conflicts of interests

- Article 4(4) which requires that ECHA 'shall serve as a point of reference by virtue of the independence and scientific and technical quality of its assessments and opinions'
- Article 14(10) which sets out the requirements on independence and incompatible
  interests for the different members of ECHA's committees, which provide the scientific
  opinions. Members of RAC, SEAC and SCCS are fully independent, also from national
  government. The members of MSC and BPC may work for national governments but
  have to act in the public interest and refrain from actions that are incompatible with their
  tasks.
- Article 19, which sets out additional rules on the declaration of interests by members of the ECHA committees and the Forum. These declarations are published, for transparency and any additional ad hoc conflict of interest needs to be declared before the meeting of the committee.
- Article 15(5) which provides that the management of conflicts will be detailed in the RoP to be adopted by the Management Board.

# Article 4(5) – General tasks

- Proposal for the ECHA Basic Regulation works with the principle of referral, whereby
  it provides the framework for ECHA's governance and sets out its general objectives
  and tasks, whilst specific tasks are set out in sectoral union legislation assigning tasks
  the Agency and listed in Annex I.
- See: Recital (4), and Article 4(3) and (6).
- The data generation mechanism (incl. the one-shot human biomonitoring study) as well as the other task that are assigned to ECHA under the legislation of the 1S1A package are intended to be covered by the 'specific tasks' of paragraph 6 of Article 4. Correspondingly, the three pieces of legislation of the 1S1A package are included in points (19)-(21) of Annex I.



#### Article 4(5)(j) – General tasks

Examples for Article 4(5)(j), under REACH:

- ECHA's conclusions and decisions in Dossier Evaluations and Follow-up Decisions
- Annex XV Restriction Reports and Assessments
   Under the restriction procedure, the European Commission can mandate ECHA to prepare Annex XV dossiers for restrictions (Article 69(1)). ECHA then produces its own assessment reports



# Chapter II: Organisation of the Agency (Articles 5-26)



#### Article 5 – Administrative and management structure

- On para 1 (c) RACs tasks cover indeed on hazards and risks
- On para 1 (e) Distribution of tasks between RAC and MSC
  - RAC to continue providing opinions on CLH
    - RAC has a wider expertise
    - The reforms proposed by the Commission enhance the capacity of RAC



#### Article 5 – Administrative and management structure

- On para 1 (e)-(f) on the names MSC and BPC, the Commission proposal keep the names of the different committees untouched since these are well established and recognizable for stakeholders. Despite some similarities of BPC and MSC they are nonetheless two distinct committees with specific tasks.
- On para 1 (g) and the role of SCCS, the proposal fully maintains the SCCS's role and methodology for assessing cosmetic ingredients:
  - Scope is not extended: substances used in cosmetics, which are characterized by daily and direct consumer exposure
  - Integration within ECHA ensures governance and support, without diluting the SCCS's specialized mandate



#### Article 6 – Composition of the Management Board

- On para 1, person is favored as these representatives represent the Commission because they are appointed ex-officio (Director, DDG or DG)
  - The same applies to organizations representing interested parties.
  - In the case of the appointees by the EP, these are referred to as experts also in other basic regulation.
- On **para 4**, the proposal aims to strike a balance between promoting gender balance without fully imposing it, which could be another barrier to appointment.



#### Article 6 - Composition of the Management Board

- On para 5, the wording on the efforts to limit turnover of the representatives of the MB stems from the <u>Common Approach on decentralised agencies</u>
- On para 5, on the term of members of the MB (4 years) and renewal (once):
  - The proposal is based on the current provisions under REACH (Article 79 (3))
  - Under the Common Approach the term is 4 years and renewable (without limit)
  - Similar approach taken in other basic regulations



#### Article 8 – Meetings of the Management Board

#### • On **para 5** :

- Under the current practice, the members of the Management Board may, in accordance with the rules of procedure, be assisted at the meetings by advisers or experts.
- The rules of procedure to be adopted by the Management Board should define the conditions / modalities of participation of advisors / experts



#### Article 9 - Functions of the Management Board

- On para 1, points (j) and (m):
  - Existing provisions of REACH (Article 108 and 103(2)),
  - to be moved to the ECHA Basic Regulation, and
  - deleted from REACH (by Article 48(5) of the proposal for the ECHA Regulation)



#### Article 10 – Voting Rules of the Management Board

- On para 3, on postponing decision in specific cases
  - The provisions allow the Management Board to adopt robust decisions which are aligned with the Staff Regulations and the Financial Regulation.
  - The preparation of some complex decision requires consulting widely within the Commission to avoid regrettable decision being adopted by the Management Board
  - These provisions are taken from the basic regulation of EMSA agreed by the co-legislators



# Article 11 – Appointment, renewal, removal of Executive Director

- On para 9, on the removal from office
  - The executive directors of Agencies are staff of the Agency (Temporary Agents). Their rights and obligations are governed by the Staff Regulations.
  - The purpose of these provisions are to ensure due process and make sure that the dismissal respects the rights and obligations of the Executive Director.
  - At the end of the day, the Management Board has the final say (decides by two thirds majority vote).
  - These provisions are coherent with the latest decisions of the co-legislators in the context of basic regulations of other agencies.



## Article 12 – Tasks and responsibilities of Executive Director

- On para 5 (e), the ED has to ensure the appropriate and timely coordination between the different bodies of ECHA.
  - This is an existing task under REACH (Article 83(2)(d) and include resolving possible internal committee divergences (Article 45 concerns inter-agency divergence)
  - In addition, the ED has to ensure timely coordination with a view to monitoring and identifying divergence under Article 45
- On para 7,
  - The possibility to locate staff to another MS granted to other agencies
  - These provisions provide a legal base should this need come up
  - Management Board and Commission have a say on this matter
  - Locating staff does not put into question the seat of the agency.



#### Overview of the current Committees and WGs

ECHA Committees (and Forum)	Working Groups under the Committees
RAC (Risk Assessment Committee)	<ul><li>CLH</li><li>Restrictions</li><li>AfA</li><li>DWD</li></ul>
SEAC (Socio-Economic Analysis Committee)	None
MSC (Member State Committee)	None
BPC (Biocidal Products Committee)	Permanent: Efficacy, Analytical Methods and Physico-chemical Properties, Human Health, Environment  Ad-hoc: Human Exposure, Assessment of Residue Transfer to Food, Environmental Exposure, Microorganisms
Forum (Enforcement Forum)	Subgroup BPRS  Several working groups run in parallel aligned with enforcement projects



#### Article 13 – Tasks of the committees

- On para 1, the proposal for the ECHA Basic Regulation works by the principle of referral, setting the framework for ECHA's governance whilst leaving the details and specificities for the sectoral legislation. Listing all specific tasks of ECHA, stemming from sectoral legislation, exhaustively in the ECHA Basic Regulation would:
  - would require constant amendment and update, via OLP as many pieces of legislation assign tasks to ECHA
    - the ECHA regulation should remain stable to provide a strengthened, predictable and reliable governance framework.
  - risks that the list of tasks in the ECHA regulation is never complete, up to date and in any case,
- On para 2 (a), on the integration of work on OELs in ECHA's mandate
- On para 3:
  - the provision in Article 13(3) is indeed intended to apply only to those scientific opinions that RAC provides pursuant to paragraph (2).
  - The number and timelines for other opinions by RAC are subject to the rules and conditions of the applicable sectoral legislation (REACH, CLP, etc.)



#### Article 14 – Membership of the Committees

Overview of the main elements concerning the Membership of the Committees:

- 1. Overview of different participants, their different roles, rights and obligations
- 2. Remuneration of rapporteurship
- 3. Capacity of RAC and SEAC & obligation to nominate members
- 4. SCCS
- 5. Other



#### 1. Overview of different participants

- Only members (regular or co-opted) can perform rapporteur work, which is required for the committee's output/opinions
- Members can decide to be accompanied by advisers to support them (technical/scientific input)
- Observers are ECHA/Commission staff and stakeholders
- Experts:
  - From MS authorities, serving in WG of committees
  - Directly identified by ECHA, remunerated by ECHA (MB decision) limited use so far



## 1. Overview of different participants

	Members	Co-opted Members	Experts	Advisers	Observers
Number	RAC/SEAC: two per MS and possibility of two more  MSC: one ('shall')	RAC/SEAC/MSC/BPC: MB setting no upon ED proposal for RAC/SEAC/SCCS.  For MSC and BPC it stays at 5.	Not set	Not set	Not set
	BPC: one + one alternate		N/	N/	N/
Voting Rights		×	X	X	X
Rapporteur work	ightharpoons		×	×	×
Mandate length	3 years, renewable	3 years, renewable (except SCCS, which is 5 years)	Unlimited	N/A	N/A
Nomination and	RAC/SEAC: MS nomination, MB	Open call, then committee	MS or ECHA	Committee Members	ECHA or Committee
appointment	appointment  MSC, BPC: MS appointment	appointment			
	SCCS: open call, MB appointment				
Payment for rapporteur work	Transfer of REACH fees (only RAC/SEAC)	Remuneration based on days needed for rapporteur work MB decision (not if co-opted is in MS employment) (RAC/SEAC)	×	X	×



## 1. Overview of different participants

Other remuneration	×	Co-opted members are remunerated for attendance as per same MB decision (not if co-opted is in MS employment)	Experts invited are remunerated for meeting attendance and other services as per same MB decision	×	×
Rights, responsibilities and characteristics	Expected to act without government instructions	To have a broad range of relevant expertise among members.	Participate ad hoc based on expertise; used in both committees and working groups (and expert groups).  BR refers to experts proposed by MS and identified directly by ECHA. MB decision to set out modalities of use of experts.	Accompanies members, member communicates name. Often employed by MS.	COM, ED/ECHA staff, stakeholder organisations, case-owners, third countries (if MB invited)
Conflict of Interest	Annual declaration, published on website + meeting-specific declaration	Annual declaration, published on website + meeting-specific declaration	Committee chairs may decide to apply the Col policy in full to long-term members. For example, this applies to the RAC DWD WG.  Meeting-specific declarations apply to all experts.	Meeting-specific declarations	Meeting-specific declarations + annual ones for ECHA staff



#### 2. Remuneration for rapporteurship

- Remuneration
  - of members (not employed by MS) is regulated by MB decision 43/2023 on remuneration of co-opted members and experts invited by the ECHA Committees or the Forum
  - Rapporteur and (co-)rapporteur work by members employed by MS is regulated by MB decision 10/2024 on the transfer of a portion of fees to the member states
    - This applies for:
      - MSC conclusion on substance evaluation procedure under REACH
      - Rapporteur work in RAC or SEAC for restriction or application for authorisation under REACH
      - Not currently CLH
  - One unified system for remuneration of rapporteurship taking into account complexity of files and available financial resources.
- Current flexibilities and good practices for nomination of members of RAC and SEAC to be encouraged as long as requirements of independence and absence of CoI are ensured
- Review of the functioning of the Committee (effectiveness and efficiency) to be undertaken in the context of the periodic performance evaluation of the agency (Article 54)

## 2. Remuneration for rapporteurship

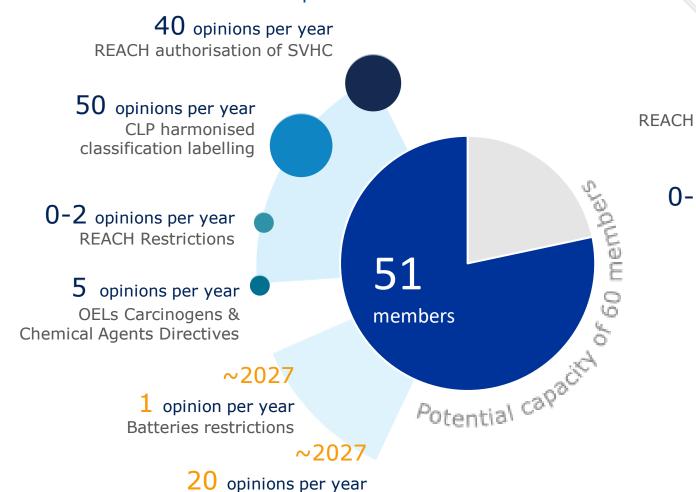
- To increase the attractivity of rapporteurship, a few measures have been put in place in by the proposal for a basic regulation and other flexibilities outside the basic regulation which need to be put in place by ECHA MB:
  - Possibility to use experts in some cases to undertake specific work against payment to facilitate the work of the committees (BR).
  - Increase the number of co-opted members to ease the burden of the committees (BR)
  - Possibility for co-opted members to be rapporteurs for all opinions but without the right to vote.
  - Increase remuneration (including of co-opted members) while defining limits and taking into account complexity and workload of assessments / opinions to be delivered. (MB)
  - Increase of staff of the Agency to support the work of the committees (LFDS)
  - Flexibility: Management Board to organise the work of the Committee through the RoP and other decisions of the MB.



#### 3. Capacity of RAC and SEAC

#### Committee for Risk Assessment

Membership and tasks

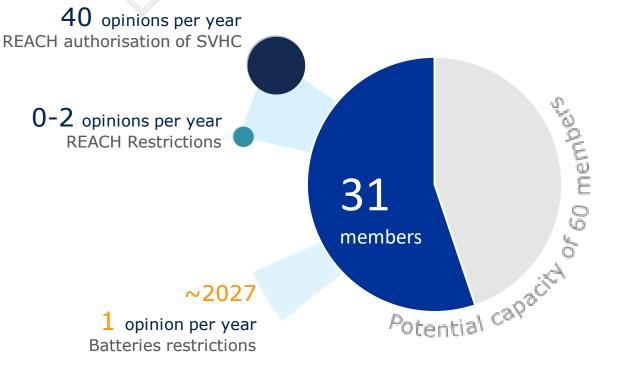


Drinking Water chemicals used in

materials in contact with drinking water

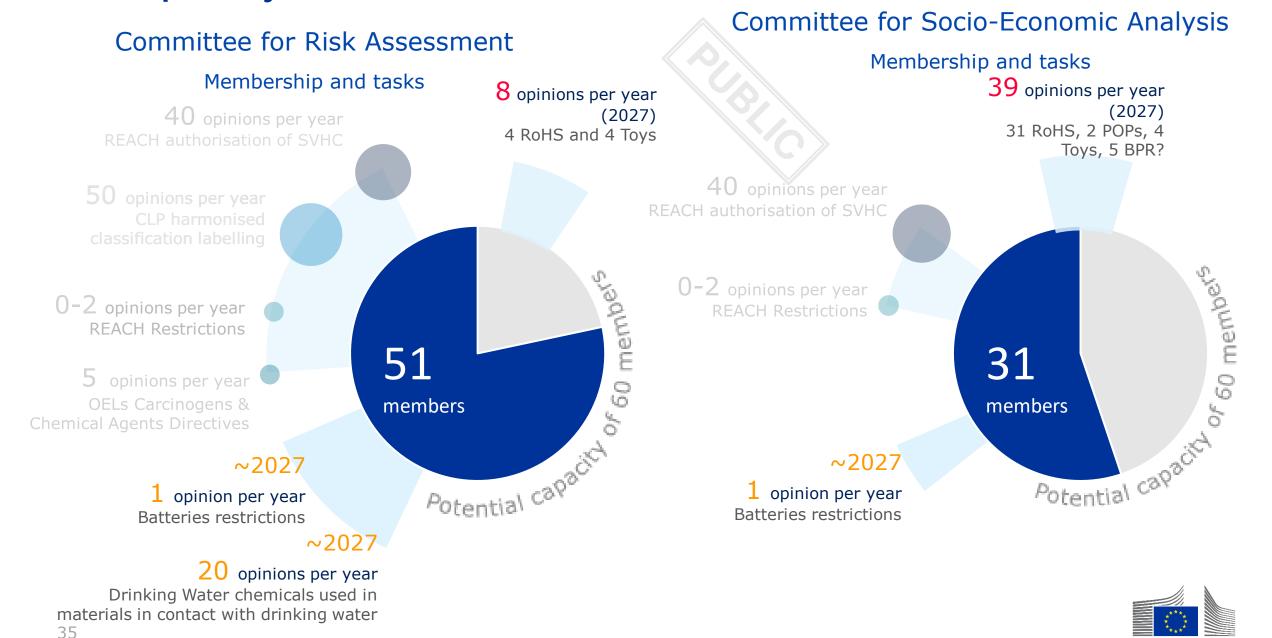
Committee for Socio-Economic Analysis

Membership and tasks





#### 3. Capacity of RAC and SEAC



#### 3. Obligation to nominate members for RAC and SEAC

- On Article 14(1) and (2),
  - Nomination by Member States of persons from other Member States is an established practice.
  - MS can nominate members for RAC and SEAC from academia, scientific institutes not necessarily from the MSCA or MS administration.
  - The proposal provides for flexibility for the Agency to organise the work of its committees and working groups. Overregulating in the basic regulation could be at the expense of the agility of the Agency.
  - The evaluation of ECHA's performance which will take place 2 years after entry into force
    of the basic regulation (Article 54): an opportunity to assess whether the reforms are
    effective and efficient
  - Introduction of obligation for nomination by MS to RAC and SEAC and the flexibility to coopt members will reduce resorting to other experts.



### 3. Obligation to nominate members for RAC and SEAC

- On the interplay with the REACH revision and future workload (also related to Article 15):
  - The need for higher legal requirements for nomination of RAC and SEAC members stems from the current capacity and workload as well as known coming workload
  - Whilst the REACH Revision intends to reduce the number of applications for authorisations, restriction dossiers are becoming increasingly complex (e.g. PFAS)
  - The proposal provides sufficient flexibility to adjust and tailor the capacity of the committees as needed, depending on workload

(see also the report of the retrospective evaluation of the committees undertaken by ECHA: AP05 (2) Annex1 retrospective evaluation Committees final report COM comments)



#### 4. SCCS

- On para 11 on the term of the SCCS members
  - Five years
  - Renewable, without restriction (as is the case for other committees)
- On the differences of rules (members term, etc.) between the SCCS and other committees:
  - SCCS operated as expert committee, not depended on nominations by MS.
  - Current model has proven effective and should hence be maintained.
- On the maximum number of members (20):
  - The core membership should be capped at 20 to ensure effective deliberation
  - Additional members may be co-opted (limit to be determined by MB) for flexibility and capacity if needed for instance for new tasks (CMR derogations)



#### 4. SCCS

- On the scope (cosmetics):
  - Cosmetics
    - 99% of SCCS mandates to date have been cosmetics
    - SCCS will remain focused on cosmetics, which have specific exposure patterns requiring tailored expertise
    - Broader consumer produce assessments remain within RAC (see also Art. 13(2)(b))
  - Professional use:
    - 'end user' under the Cosmetics Regulation covers both (consumers and professionals)
    - safety assessment of substances used in cosmetic products for professional use are covered
    - Notes of Guidance of the SCCS could be adjusted to provide information on the safety of such products and professionals (hairdressers, nail salons, etc.) using them
- Current name well-established and recognisable for stakeholders



#### 4. SCCS

- On SCCS as a standalone committee (also see slide 18)
  - RAC and SCCS have complementary roles
  - cosmetics are the only consumer products with a sector-specific regulation requiring systematic, detailed ingredient safety assessments for each regulatory measure taken.
  - SCCS ensures this expertise is preserved and regulatory continuity
  - avoids overloading RAC with tasks outside its current scope.
  - Embedding the SCCS in ECHA with tailored support makes more efficient use of resources



#### 5. Other

- On para 15 and its scope of application
  - This provision applies to all members (nominated by MS and co-opted)
  - It concerns the arrangements for the applicable financial renumeration which is paid either to them, or in case they are employed by a Member State, to that state.
  - The tasks and the renumeration are determined by the MB following positive opinion of COM.



#### Article 15 – Functioning of the Committees

- On the remuneration:
  - Currently MS are compensated for the rapporteuship work for authorisations and restrictions from a proportion of fees levied by ECHA under REACH.
  - For the rapporteurship work in the future, there should be one unified system for compensation for MS for all authorisations, restrictions or derogations deriving from all the legislation implemented by ECHA.
  - Remuneration or compensation should derive from ECHA budget.
  - Remuneration of members of RAC and SEAC from MS are governed by agreements between ECHA and MS
- Mitigation by the agency and its Management Board of any side effects of the broadening of the scope of the committees and their membership.
- Avoid as far as possible overregulating in the basic regulation and leave a margin of manoeuvre to the agency to organise the work of its committees through the RoP
- On para 4 and the need for approval of the rules of procedure:
  - The approach between RAC, SEAC and SCCS should indeed be aligned



### Article 16 – Use of Experts

- On para 1,
  - the Agency to be able to rely on the services of experts for
    - Committees
    - Working groups of committees, forum
    - Performance of other relevant tasks, where justified
  - Only members and co-opted members can act as rapporteurs
- On para 2: Management Board to establish procedural arrangements and EHCA to ensure objective impartiality of experts
- Co-opting members in committees should in principle reduce the use of other experts in committees.



#### Article 17 – Forum

- The provisions relating to the Forum are nearly identical to the existing provisions governing the Forum (Article 86 of REACH).
- Possibility to appoint alternate members of the Forum (3 per MS) has been added to the legal text to reflect current practice, set out in the RoP of the Forum.



#### Article 19 – Qualifications and interests

#### On para 2

- ECHA has a comprehensive policy on the management of conflict of interest adopted by the Management Board
- The RoP of the committees adopted by the Management Board cover aspects the aspects on Col management.

#### On para 3,

- Current provision of REACH (Article 88(3))
- intended to provide an assurance, further to the annual declaration foreseen in para 2, for any potential additional interests that could be considered prejudicial
- These might only manifest themselves at a specific meeting (ad hoc), in which case the member shall not vote on the point



#### Article 23 – Decisions subject to appeal

Listing the specific decisions of sectoral legislation for which a right of appeal to the Boad of Appeal exists

- The proposal for the ECHA Regulation is based on the principle of referral
- The added clarity such list could bring would be outbalanced by the inflexibility and need for subsequent amendments that this would entail.
  - Specifically, each time a possibility for appeal would be provided in the sectoral legislation, the ECHA Basic Regulation would require amendment as well.





#### Round two

- Chapter III: Financial Provisions (Articles 27-33)
- Chapter IV: Staff (Articles 34-36)



# Chapter III: Financial Provisions (Articles 27-33)



### Other measures to increase sustainability of ECHA's financial model

The Commission has initiated other measures to increase the sustainability of ECHA's financial model. Specifically, via amendments of the Fee Regulations:

- Under the BPR to adapt fees to inflation (increase of 19.5%), <u>Commission Implementing</u> <u>Regulation (EU) 2025/1490</u>, entered into force on 14 August.
- Under the REACH Regulation to adapt fees to inflation (increase of 19.5%) and change the SME verification system from ex post to ex ante. The draft measure is currently undergoing written vote in the REACH Committee.



#### Article 27(5) – Single programming document

- Provisions on programming documents:
  - The drafting is standard.
  - Additional provisions on programming derive also from the financial rules.
  - Guidance is also provided in a communication of the Commission on programming and reporting.



#### Article 29 – Structure of the budget and reserve fund

#### On para. 3:

- One budget and one unitary EU financial contribution to ECHA (currently 3 budgets and 3 EU contributions with adverse effects)
- Income from fees and charges + EU financial contribution
- A reserve to mitigate fluctuation of income from fees and charges (REACH and BPR)
- Reserve is limited and the sole purpose is to mitigate the fluctuation of fee revenues.
- 8% limit based on historical data of fluctuation + transparency towards the budgetary authority
- Sustainability of financing through various measures and action including revision of fee regulation



### Chapter IV: Staff (Articles 34-36)





#### Round three

- Chapter V: Information and Communication (Articles 37-39)
- Chapter VI: Cooperation (Articles 40-45)



# Chapter V: Information and Communication (Articles 37-39)



#### Article 37 – Transparency and communication

- On para. 3 (and recital (28):
  - ECHA has established a communications strategy (common approach)
  - In its communication ECHA targets efforts to the needs and requirements for each group EU Institutions, Member State Authorities, Industry, groups representing the environment, the public and workers.
  - ECHA has obligation under Article 123 of REACH to communicate information to the public on risks of substances
  - 9 FTEs are assigned for the communication of data to the public and around EUR 3 million. (source ECHA)
  - Against a background of scarce resources, the communication activities should be proportionate to the obligations of the agency and not at the expense of the other core task.



### Chapter VI: Cooperation (Articles 40-45)



#### Article 41 – Cooperation with stakeholders

- Provisions kept high level to take into account specific requirements in sectoral legislation
- Stakeholders intends to cover all of ECHA's stakeholders, including industry



#### Article 42 – International regulatory cooperation

 On para 6, the intention of the proposal and use of the term originator principle is indeed to align with the definition of the 1S1A package, to avoid any divergence. The same principles should apply.



#### Article 43 – Research and innovation

- These provisions scope the areas of research in which the agency could participate in EU research programmes
- Legal base for the eligibility of participation of ECHA in EU research programmes (e.g. Horizon Europe).
- Resources are allocated on an ad hoc basis. Currently ECHA has been allowed to use 2 FTEs for its participation in PARC project but is not entitled to any financial contribution given that that there no legal base for the eligibility of ECHA in its founding act (REACH).
- The obligations of ECHA under the sectoral legislation such the common data platform regulation apply (the basic regulation works by referral)



#### Article 43 – Research and innovation

On the indicators of performance (page 80) and roadmap for phasing out animal testing for chemical safety assessments

- Roadmap plans that:
  - that ECHA, EFSA, EMA, Member State experts, stakeholders and relevant Commission services (including JRC) will be part of the Roadmap Steering Team which will oversee the roadmap implementation.
  - That EU agencies and JRC will also take part in other collaborative structures dedicated to animal-free methods such as a regulatory science community on this.
  - A recommendation to the EU agencies is to set up a Working Group on animal-free approaches within the EU Agency Network to foster coordination and collaboration
- Roadmap will specify indicators, some have been listed in the proposal since ECHA will play a
  key role in its implementation. Additional indicators might be developed and deployed by
  Commission services (including JRC), the EU Agencies, Member States and stakeholders



## Article 45 – Divergence of scientific opinion with other Union Agencies

- Intention of the proposal is to align the wording with the provisions on divergence of opinions in the 1S1A package to ensure consistency.
- A few minor differences between the provisions are necessary and appropriate:
  - The reference to 'authority' has been replaced by the reference to the 'agency'
  - The reference to the objective has not been included because the different pieces of legislation assigning tasks to ECHA have different (primary and secondary) objectives, which all ought to be considered.





#### Round Four

- Chapter VII: Delegate Powers and Committee Procedure (Articles 46-47)
- Chapter VIII: Amendments (Articles 48-51)
- Chapter IX: Transitions Provisions (Articles 52-53)
- Chapter X: General and Final Provisions (Articles 54-58)



## Chapter VII: Delegate Powers and Committee Procedure (Articles 46-47)



### Chapter VIII: Amendments (Articles 48-51)



#### Article 48 – Amendment REACH – correlation table

#### On the **correlation table** in Annex II of the proposal

- For the sectoral legislation which currently refers to articles within REACH which will move to the ECHA Regulation, for instance:
  - Article 74(2) of the biocidal products regulation:
     'Articles 78 to 84, 89 and 90 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis taking into account the role of the Agency with respect to this Regulation.
  - Article 37(4) of CLP:

'The Committee for Risk Assessment of the Agency set up pursuant to Article 76(1)(c) of Regulation (EC) No 1907/2006 ....'

- Article 11(6) of the Drinking Water Directive:
  - 'The Committee for Risk Assessment of ECHA set up pursuant to point (c) of Article 76(1) of Regulation (EC) No 1907/2006 shall issue an opinion '
- To facilitate the cross-references and increase transparency



#### Article 49 – Amendment BPR

On **para 2**, the possibility for the BPC to request SEAC to contribute to the work of the BPC for certain tasks

- Background:
  - For certain active substances (meeting the criteria in Article 5(1), 'exclusion substances'), the BPC has to assess whether the conditions for derogations to exclusion set out in Article 5(2) are met when providing its opinion on the approval of the active substance
  - One of the derogation criteria (Article 5(2)(c)) requires an assessment of the 'impact on society deriving from non-approving the active substance compared with the risks from the use of the substance'
  - The BPC currently lacks the skills to perform the socio-economic analysis which is part of this assessment and had difficulties providing comprehensive opinions on this.



#### Article 49 – Amendment BPR

- SEAC would provide a contribution on the socio-economic analysis to the BPC
- This would complement the considerations on availability and suitability of alternatives as part of a comprehensive analysis
- Conclusions (on whether the conditions for derogation to exclusion are met) are to be decided and agreed by the BPC
- Details, practical arrangements and timelines will be defined in the implementation phase via Rules of Procedure)
- Proposed to make synergies and ensure better consistency in the way socioeconomic considerations are considered in the assessment of chemicals
- Not for all substances which are candidate for substitution (Article 10(1) of the BPR) but only those meeting the first criterion for substitution (Article 5(2), exclusion substances)
- Workload would be ca. 5 contributions of SEAC to the BPC, per year (p. 37 of the Explanatory Memorandum)



#### Article 49 – Amendment BPR

- On the available data:
  - The burden of proof (to demonstrate the derogation criteria are fulfilled) rests on the applicant (Article 6(1)(c)) and there is a risk of a negative opinion if the data is not provided
  - Applicants submit their own socio-economic analysis
  - ECHA guidance foresees this as well
- Relationship between ongoing work on this and the proposal
  - The ad hoc WG of the BPC is related to analysis of Art 5(2) as a whole, while SEAC will look only at the socio-economic aspects
  - The input from SEAC to the BPC would feed into the work of the ad hoc WG



# Chapter IX: Transitions Provisions (Articles 52-53)



# Chapter X: General and Final Provisions (Articles 54-58)



#### Article 56 – Operating conditions – Local office

- The basic regulations of some agencies include this possibility.
- The aim is to have a legal basis should there be a need in the future.
- There are no plan in our knowledge that such plans are envisage by the Agency
- Locating staff on another MS is subject to the approval of the Management Board and of the Commission.



### Thank you





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