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REQUEST FOR CONTRIBUTION

From:	General Secretariat of the Council
To:	Ad hoc Working Party on the ECHA Basic Regulation
Subject:	ECHA Basic Regulation: Follow-up to AHWP ECHA meeting on 28 October 2025 - CALL FOR COMMENTS

As a follow-up to the 28 October 2025 meeting of the Ad hoc Working Party on the ECHA Basic Regulation, delegations will find attached the Commission presentations shown at the meeting.

Delegations are also kindly invited to submit their written comments including concrete text proposals on the Presidency compromise text published with WK 14088/2025.

Comments should be sent to the Presidency [redacted], with a copy to the Commission ([redacted]) and the Council Secretariat ([redacted]) by **Thursday 30 October 2025 cob**.

Proposal for ECHA Basic Regulation - Further explanations

28 October 2025

DG GROW F.1

Ad Hoc Working Party on ECHA Basic Regulation

European Commission

Overview

- RAC and SEAC
- ECHA's Secretariat and Management Board (MB)
- 'safe use' examples

RAC and SEAC

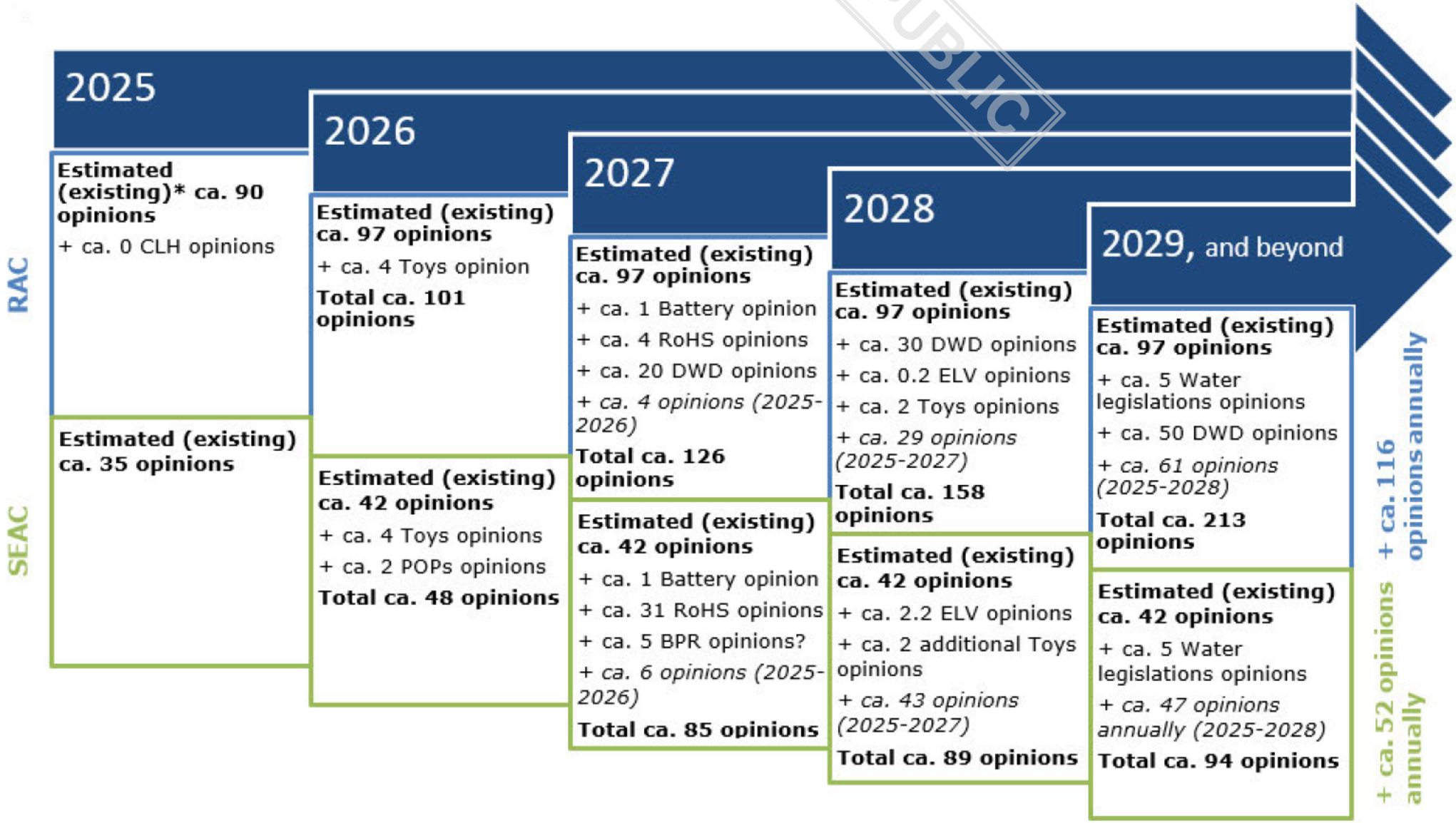
Rationale of the reforms

- The current framework stipulates that RAC and SEAC members are nominated by Member States (MS) and appointed by the Management Board, with up to five additional co-opted members selected by the Committee (Article 85(1), (2) and (4) of REACH).

- RAC and SEAC are well below the full capacity of 60 MS-nominated members (two possible nominations per 27 MS and three EEA countries). This is despite a recent encouraging increase: currently, RAC has 50 and SEAC 30 MS-nominated members.

- Against this background, the Commission has proposed reforms in the ECHA Basic Regulation proposal which is expected to provide long-term solutions to improve the governance and increase capacity of RAC and SEAC.

Workload in the coming years (source: ECHA)



Evolution of ECHA budget since 2021 (current MFF)

Funding area	Budget type	2021	2022	2023	2024	2025
REACH / CLP	Initial budget	93,426,227	95,112,163	99,965,024	105,781,565	111,985,260
	1st Amendment				105,828,766	
	2nd Amendment	90,097,897	96,612,200	99,601,523	106,663,766	110,009,538
BPR	Initial budget	13,247,924	11,919,000	12,711,675	14,074,313	15,069,812
	1st Amendment				14,111,813	
	2nd Amendment	12,947,924	13,112,477	13,239,434	14,198,398	16,768,427
Environmental policy	Initial budget	5,607,100	4,844,971	5,047,743	7,277,969	10,904,890
	1st Amendment				5,687,873	
	2nd Amendment	5,285,100	4,844,971	5,132,743	5,745,790	7,323,952
ECHA total (initial budget)		112,281,251	111,876,134	117,724,442	127,133,847	137,959,962
ECHA total (final budget)		108,330,921	114,569,648	117,973,700	126,607,954	134,101,917

Committee membership requirements - Article 14

- The requirements for membership stay the same as under the current framework:
  - There must be sufficient support from the nominating MS to the committee members, Art. 14(9).
  - There must be appropriate coordination between the committee members and the nominating MS authorities, Art. 14(12).
- Further details of the committee membership can be defined in the committees' Rules of Procedure, which is adopted by the Management Board, Art. 15(5).
- There are no rules in place for nationality requirements currently, and the Basic Regulation proposal doesn't introduce any either. The current practice is that committee members may be nominated by EU Member States or EEA/EFTA countries. Nominations may also be submitted on behalf of another Member State. Committee members may be EU nationals or nationals of non-EU countries.

Co-opted members of the Committees - Article 14(6)

- Besides Member State nominees, the committees and the Forum may co-opt max 5 members to cover specific scientific or technical areas. There are currently 4 co-opted members in SEAC and 5 in RAC.
- The Basic Regulation foresees that the number of RAC and SEAC co-opted members can be higher (MB decision).
- Co-opted members are directly appointed by RAC/SEAC. There is no nationality requirement in the current legislation or the Basic Regulation proposal. They can be EU or third-country nationals.
- Co-opted members have no voting rights but can act as rapporteurs.
- They receive the same reimbursements as MS-nominated members (travel, accommodation and subsistence allowances –see MB Decision 24/2025).
- In addition, they are remunerated for attending meetings but do not get a salary solely for being co-opted – see MB Decision 43/2023.
- If appointed as rapporteurs, they sign a service contract with ECHA and are paid similarly to MS-nominated member rapporteurs.

Rapporteurs - Article 14(7) and (8)

- As per REACH (Art 87), every committee opinion requires a rapporteur (or co-rapporteurs) to be appointed. MS-nominated and co-opted committee members can be rapporteurs. Other experts cannot (Article 16). The Basic Regulation does not change this.
- The committees' expanded mandate requires more rapporteurs, which, in turn, requires increased membership both in terms of number and available expertise. The Basic Regulation addresses this issue under committee membership (Art 14).
    - MS-nominated members for RAC and SEAC: 2 +2
    - Co-opted members in RAC and SEAC: number to be set by the Management Board, according to the needs and the availability of resources
    - In addition, establishing a reasonable level of payments for rapporteurs' work under any legislation will be crucial to make the committees' work sustainable; the lack of payment for rapporteur work under legislation other than REACH has been identified as an issue that needs addressing.

Payments – Article 14(15) and 14(15a)

- Currently REACH (Art. 74(4)) and the REACH Fee Regulation (Art. 14) set out the rules for the **transfer of a portion of fees to MS**. The Basic Regulation does not change this. It allows for a similar framework to be put in place if any other sectoral legislation includes fee collection.
  - A proportion of fees is transferred to MS (= payments are made **to MS authorities who are in a contractual relationship with the (co)rapporteur committee member**) for REACH **restriction** and **AfA opinions.**
  - A proportion of fees is also transferred for Substance Evaluation.
  - The daily amount and maximum number of payable days are defined in a Management Board Decision (MB Decision 12/2024), which requires the positive opinion of the Commission.
- Currently the **remuneration paid to co-opted committee members** for meeting attendance, rapporteur work and other services is defined in a MB Decision (43/2023). Under the Basic Regulation, it will be possible to extend the remuneration of co-opted members to work done under other sectoral legislation too. This MB decision will require the positive opinion of the Commission.

Type of payments for committee work

MS-nominated members	Transfer of fee proportion to Member State for (co) rapporteur work Scope: REACH: restrictions and authorisation applications
Co-opted members	Direct payment for meeting attendance (daily rate) Direct payment for (co) rapporteur work Scope REACH restrictions and authorisation applications and OELs (current practice)
Experts	Direct payment for meeting attendance (daily rate) Direct payment for other services (rapporteur work excluded)
All	Travel, hotel costs and daily allowance in case of meeting attendance

Note: Member States also receive a transfer of a proportion of fees for Substance Evaluation work, but this does not concern RAC and SEAC..

Use of experts – Article 16

- Current situation (Art. 87 REACH): the use of experts (in the committees, in the Forum and in the working groups of the Committees) is possible under current framework but the use in practice has been limited so far.
- The Basic Regulation provides an opportunity to increase the scope:
  - The Management Board will adopt a decision for the procedure for and the scope of the use of experts. The use of the experts will also be regulated in the committees' RoP.
  - ECHA will keep a public list of experts.
  - MS will be able to appoint experts and ECHA will have the possibility to identify experts directly (governed by the Management Board decision).
  - The Committee members' obligations on independence, contractual and payment modalities apply mutatis mutandis to the experts.

Conflict of Interest prevention and management – Article 4(4), 14(10), 15(5) and 19

- Independence requirements (including conflict of interest (CoI) prevention and management) will continue to be defined in the committees' RoP and ECHA's CoI Policy and Procedure (both adopted by the MB).
  - Committee members abide by ECHA's CoI policy, including exclusion criteria (e.g., no parallel industry work possible). They must submit and keep updated a declaration of interest and a CV. These are published. Examples:
    - RAC - Published Declarations of Interest and CVs · Starter Portal
    - SEAC - Published Declarations of Interest and CVs · Starter Portal
  - In every committee meeting and before taking up a rapporteur assignment for an opinion, committee members make a separate declaration regarding agenda points in that meeting or the specific opinion. In case of conflicts, they may not take up rapporteur work and may not participate in the adoption of some opinions.

Working groups – Article 5(2), 15(5) and 17(5)

- Current situation: Working Groups (WG) are established in the committees' RoPs. Each WG has a Terms of Reference, adopted by the committee.
- Under the Basic Regulation this system will continue:
  - WG to be established in the committees' RoPs.
  - The RoPs will define the general composition and chairperson of each WG.
  - Each WG applies the general provisions as defined in RoPs for WG.
  - WGs support the parent Committee in preparing opinions and decisions. They handle specific dossiers or regulatory tasks. Delegation of tasks to the WG is done via the RoP.

Expert Groups

- **Expert groups** are not in the scope of the proposed regulation. Expert groups are not part of the Committees. They are advisory entities, not involved in the opinion-making (operate independently from the Committees).
- They are not formal bodies of ECHA. The decision on setting up expert groups was taken by Member States in the framework of CARACAL. Expert groups are composed of MS experts and selected stakeholders.
- Examples: **PBT**, **ED**, **Nanomaterials** expert groups.

ECHA's Secretariat and Management Board

ECHA Secretariat (ECHA staff) - Art. 4(5)(a), 5(1)(i), 8(8), 15(3)

- The ECHA Secretariat staff will continue to perform technical, scientific and administrative tasks to support the committees:
  - Administrative: facilitates the opinion development, meeting management, membership and stakeholder administration, access rights, declarations (independence) and financial arrangements.
  - Technical - scientific: assisting the rapporteur (committee member) in ensuring the scientific quality and consistency of the content of the opinions.
  - Ensure appropriate coordination between the committees.
  - The Secretariat, under the leadership of the Executive Director, will put in place the necessary internal measures to ensure that the support provided to committees fully respects the independence and prerogatives of committee members and rapporteurs for opinion.

Management Board roles regarding the Committees

- Governance and strategic steering role, appoints the MS-nominated members of RAC and SEAC, defines the financial arrangements for the payment of rapporteurs and co-rapporteurs and adopts the Rules of Procedure of the committees.
- Decisions expected to be adopted by the Management Board with respect to the committees:
  - RoPs of the committees (revision of existing MB decision MB/10/2021)
  - Number of co-opted members (new)
  - List of tasks for which payments are made (new)
  - Payment modalities for committee members (revision of existing MB Decision MB/35/2023 on remuneration and, existing MB Decision MB/07/2024 on transfer of compensation)
  - Decision on the use of experts (experts will be used in WGs and EGs) (partly new, partly existing)
  - CoI policy (revision of existing MB Decision, see document 10/09/2023)

'safe use' examples

Safe use in sectoral Union legislation (CLP and BPR)

'Safe use' is not a new concept introduced into the ECHA Regulation. It's a term used in different pieces of chemicals legislation within ECHA's mandate. **What constitutes 'safe use' in a specific case, depends on the applicable legislation**. 'Safe use' is regulated under sectoral Union legislation:

1. Article **34 CLP Regulation** (EC) No 1272/2008:

   *1. By 20 January 2012, the Agency shall carry out **a study on the communication** of information to the general public **on the safe use of substances** and mixtures and the potential need for additional information on labels. This study shall be carried out in consultation with competent authorities and stakeholders and drawing as appropriate on relevant best practice.*

2. Article **67(1) BPR Regulation** (EU) No 528/2012:

   *1. From the date on which the Commission adopts an implementing Regulation providing that an active substance is approved, as referred to in point (a) of Article 9(1), the following up-to-date information held by the Agency or the Commission on that active substance **shall be made publicly** and easily available free of charge:*

   *[…] (g) **the guidance on safe use** provided in accordance with Annexes II and III;*

Safe use in sectoral Union legislation (REACH)

3. Article **77 REACH (Tasks of the Agency):**

   1. The Secretariat shall undertake the following tasks:

   […] providing guidance to stakeholders including Member State competent authorities on communication to ***the public of information*** *on the risks and* ***safe use of substances,*** *on their o*wn, in preparations or in articles;

4. Article **119 of REACH (electronic public access):**

   1.The following information held by the Agency on substances whether on their own, in preparations or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e):

   […] (g) the ***guidance on safe use*** *provided in accordance with sections 4 and 5 of Annex VI;*

5. Article **123 REACH (Communication to the public of information on risks of substs.):**

   The competent authorities of the Member States shall inform the general public about the risks arising from substances where this is considered necessary for the protection of human health or the environment. The Agency, in consultation with competent authorities and stakeholders and drawing as appropriate on relevant best practice, ***shall provide guidance*** *for the communication of information* ***on*** *the risks and* ***safe use of chemical substances****, on their own, in preparations or in articles, with a view to coordinating Member States in these activities.*

Safe use in sectoral Union legislation (Cosmetics, Medical Devices and Toys)

6. Article **15(3) Cosmetics Regulation** (EC) No 1223/2009:

   3. *By 11 January 2012, the Commission shall ensure that appropriate guidance is developed with the aim of enabling a harmonised approach to the development and use of overall exposure estimates in **assessing the safe use of CMR substances**. This guidance shall be developed in consultation with the SCCS, the ECHA, the EFSA and other relevant stakeholders, drawing, as appropriate, on relevant best practice.*

7. Article **18(1) Medical Devices Regulation** (EU) 2017/745:

   1. *The manufacturer of an implantable device shall provide together with the device the following:*

      *[…] (d) any other information to ensure **safe use** of the device by the patient, including the information in point (u) of Section 23.4 of Annex I.*

8. Article **6(1)** Proposal for a Regulation on the **Safety of Toys:**

   1. *Where necessary **to ensure their safe use**, toys shall bear a general warning specifying appropriate user limitations. The user limitations shall include at least the minimum or maximum age of the user and, where appropriate, the required abilities of the user, the maximum or minimum weight of the user and the need to ensure that the toy is used only under adult supervision*

Safe use in sectoral Union legislation (General Product Safety)

9. Article **6(1) General Product Safety** Regulation (EU) 2023/988:

   1. When assessing whether a product is a safe product, the following aspects in particular shall be taken into account:

   (d) the presentation of the product, the labelling, including the labelling regarding age suitability for children, any warnings and instructions for its safe use and disposal, and any other indication or information regarding the product;

10. Article **35(1) General Product Safety** Regulation (EU) 2023/988:

    1. In the case of a product safety recall, or where certain information has to be brought to the attention of consumers to ensure the safe use of a product ('safety warning'), economic operators, in accordance with their respective obligations as provided for in Articles 9, 10, 11 and 12, and providers of online marketplaces in accordance with their obligations as provided for in Article 22(12), shall ensure that all affected consumers that can be identified are notified directly and without undue delay. Economic operators and, where applicable, providers of online marketplaces that collect their customers' personal data shall make use of that information for recalls and safety warnings.

Safe use in sectoral Union legislation (General Product Safety) (part 2)

11. Article **22 (12) General product safety** Regulation (EU) 2023/988:

12. *Providers of online marketplaces shall cooperate with the market surveillance authorities, with traders and with relevant economic operators to facilitate any action taken to eliminate or, if that is not possible, to mitigate the risks presented by a product that is or was offered online through their services. In particular, providers of online marketplaces shall:*

(a) ensure that they provide appropriate and timely information to consumers including by:

(i) directly notifying all affected consumers who bought through their interfaces the relevant product in the event of a product safety recall of which they have actual knowledge or where certain information has to be brought to the attention of consumers ***to ensure the safe use of a product*** *(the 'safety warning') in accordance with Article 35 or 36, or both;*

Thank you

Proposal for ECHA Basic Regulation - Sectoral Union legislation (Annex I) assigning tasks to RAC and SEAC

28 October 2025

DG GROW F.1

Ad Hoc Working Party on ECHA Basic Regulation

European Commission

Sectoral Union legislation (Annex I) assigning tasks to RAC and SEAC

RAC tasks under REACH

1. Article 60(4), Granting of authorisations:

If an authorisation cannot be granted under paragraph 2 or for substances listed in paragraph 3, an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. This decision shall be taken after consideration of all of the following elements and ***taking into account the opinions of the Committee for Risk Assessment*** *and the Committee for Socio-economic Analysis referred to in Article 64(4)(a) and (b):*

(a) the risk posed by the uses of the substance, including the appropriateness and effectiveness of the risk management measures proposed;

(b) the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties;

(c) the analysis of the alternatives submitted by the applicant under Article 62(4)(e) or any substitution plan submitted by the applicant under Article 62(4)(f), and any third party contributions submitted under Article 64(2);

(d) available information on the risks to human health or the environment of any alternative substances or technologies.

2. Article 64(1): Procedure for authorisation decisions

The Agency shall acknowledge the date of receipt of the application. The Agency's ***Committees for Risk Assessment*** *and Socio-economic Analysis shall give their draft opinions within ten months of the date of receipt of the application.*

3. Article 64(3): Procedure for authorisation decisions

In preparing its opinion, ***each Committee*** *referred to in paragraph 1* ***shall first check that the application includes all the information specified in Article 62*** *that is relevant to its remit. If necessary, the Committees shall, in consultation with each other,* ***make a joint request to the applicant for additional information*** *to bring the application into conformity with the requirements of Article 62. The Committee for Socio-economic Analysis may, if it deems it necessary, require the applicant or request third parties to submit, within a specified time period, additional information on possible alternative substances or technologies. Each Committee shall also take into account any information submitted by third parties.*

RAC tasks under REACH (part 2)

4. *Article 64(4a):* Procedure for authorisation decisions

*The **draft opinions shall include** the following elements:**(a) Committee for Risk Assessment**: an assessment of the risk to human health and/or the environment arising from the use(s) of the substance, including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives;*

5. *Article 64(5):* Procedure for authorisation decisions

***The Agency shall send these draft opinions to the applicant** by the end of the deadline set out in paragraph 1. Within one month of receipt of the draft opinion, the applicant may provide written notice that he wishes to comment. The draft opinion shall be deemed to have been received seven days after the Agency has sent it.*
If the applicant does not wish to comment, the Agency shall send these opinions to the Commission, the Member States and the applicant, within 15 days of the end of the period within which the applicant may comment or within 15 days of receipt of notice from the applicant that he does not intend to comment.
*If the applicant wishes to comment, he shall send his written argumentation to the Agency within two months of the receipt of the draft opinion. **The Committees shall consider the comments** and adopt their final opinions within two months of receipt of the written argumentation, taking this argumentation into account where appropriate. **Within a further 15 days the Agency shall send the opinions,** with the written argumentation attached, **to the Commission, the Member States and the applicant**.*

RAC tasks under REACH (part 3)

6. Article 69(4): Preparation of a proposal (restriction)

If a Member State considers that the manufacture, placing on the market or use of a substance on its own, in a ►M3 mixture ◄ or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed it shall notify the Agency that it proposes to prepare a dossier which conforms to the requirements of the relevant sections of Annex XV. If the substance is not on the list maintained by the Agency referred to in paragraph 5 of this Article, the Member State shall prepare a dossier which conforms to the requirements of Annex XV within 12 months of the notification to the Agency. If this dossier demonstrates that action on a Community-wide basis is necessary, beyond any measures already in place, the Member State shall submit it to the Agency in the format outlined in Annex XV, in order to initiate the restrictions process.
The Agency or Member States shall refer to any dossier, chemical safety report or risk assessment submitted to the Agency or Member State under this Regulation. The Agency or Member States shall also refer to any relevant risk assessment submitted for the purposes of other Community Regulations or Directives. To this end other bodies, such as agencies, established under Community law and carrying out a similar task shall provide information to the Agency or Member State concerned on request.
***The Committee for Risk Assessment** and the Committee for Socio-economic Analysis **shall check whether the dossier submitted conforms to the requirements** of Annex XV. Within 30 days of receipt, the respective Committee shall inform the Agency or the Member State suggesting restrictions, as to whether the dossier conforms. If the dossier does not conform, the reasons shall be given to the Agency or the Member State in writing within 45 days of receipt. The Agency or the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the Committees, otherwise the procedure under this Chapter shall be terminated. The Agency shall publish without delay the intention of the Commission or of a Member State to instigate a restriction procedure for a substance and shall inform those who submitted a registration for that substance.*

RAC tasks under REACH (part 4)

7. Article 70: Agency opinion: Committee for Risk Assessment (restriction)

Within nine months of the date of publication referred to in Article 69(6), ***the Committee for Risk Assessment shall formulate an opinion as to whether the suggested restrictions are appropriate*** *in reducing the risk to human health and/or the environment, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the Member State dossier or of the dossier prepared by the Agency at the request of the Commission, and the views of interested parties referred to in Article 69(6)(a).*

8. Article 76(2): Composition

The Committees referred to in points (c), (d) and (e) of paragraph 1 (hereinafter referred to as the Committees) and the Forum ***may each establish working groups.*** *For this purpose* ***they shall adopt****, in accordance with their rules of procedure,* ***precise arrangements*** *for delegating certain tasks to these working groups.*

9. Article 76(3): Composition

The Committees and the Forum may, if they consider it appropriate, seek advice on important questions of a general scientific or ethical nature from appropriate sources of expertise.

10. Article 77(3): Tasks

The Committees shall undertake the following tasks:(a) performing the tasks allotted to them under ►M3 Titles VI to X ◄ ;(b) at the Executive Director's request, providing technical and scientific support for steps to improve cooperation between the Community, its Member States, international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on sound management of chemicals in developing countries;(c) at the Executive Director's request, drawing up an opinion on any other aspects concerning the safety of substances on their own, in ►M3 mixtures ◄ or in articles.

RAC tasks under REACH (part 5)

11. Article 85(9): Establishment of the Committees

*Each Committee shall draft a proposal for its **own rules of procedure**, to be approved by the Management Board, within six months of the Committees first being appointed.*

12. Article 110(2): Relations with relevant Community bodies

*The Executive Director, **having consulted the Committee on Risk Assessment** and the European Food Safety Authority, shall establish **rules of procedure concerning substances** for which an opinion has been sought in a **food safety context**. These rules of procedure shall be adopted by the Management Board, in agreement with the Commission. This Title shall not otherwise affect the competences vested in the European Food Safety Authority.*

13. Article 110(4): Relations with relevant Community bodies

*The Executive Director, having consulted the **Committee on Risk Assessment**, the Committee on Socio-economic Analysis and the Advisory Committee on Safety, Hygiene and Health Protection at Work, **shall establish rules of procedure concerning worker protection issues.** These rules of procedure shall be adopted by the Management Board, in agreement with the Commission.This Title shall not affect the competences vested in the Advisory Committee on Safety, Hygiene and Health Protection at Work and the European Agency for Health and Safety at Work.*

RAC tasks under CLP

1. **Article 37(4): Procedure for harmonisation of classification and labelling of substances**

The Committee for Risk Assessment of the Agency *set up pursuant to Article 76(1)(c) of Regulation (EC) No 1907/2006 shall adopt an opinion on any proposal submitted pursuant to paragraphs 1 or 2 within 18 months of receipt of the proposal, giving the parties concerned the opportunity to comment.* ***The Agency shall forward*** *this opinion and any comments to the Commission.*

RAC tasks under Drinking Water Directive

1. **Article 11(6): Minimum hygiene requirements for materials that come into contact with water intended for human consumption**

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 on any application submitted pursuant to paragraph 5 within a time limit to be set out in the delegated acts referred to in that paragraph. Further procedural provisions on the application process and on the issuing of opinions by the Committee for Risk Assessment of ECHA may also be included in those delegated acts.*

RAC tasks under Batteries Regulation

1. Article 86(7): Restriction procedure for substances

The Committee for Risk Assessment, set up pursuant to Article 76(1)(c) of Regulation (EC) No 1907/2006, and the Committee for Socioeconomic Analysis, set up pursuant to Article 76(1)(d) of that Regulation, shall check whether the restriction dossier submitted conforms to the requirements of Annex XV to that Regulation. Within 30 days of receipt of the dossier, the respective Committee shall inform the Agency or the Member State suggesting restrictions, as to whether the dossier conforms. If the dossier does not conform, the reasons shall be given to the Agency or the Member State in writing within 45 days of receipt. The Agency or the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the respective Committee, otherwise the procedure under this Article shall be terminated.

2. Article 87(1): Opinion of the Agency Committees

1. Within 12 months of the date of publication referred to in Article 86(9), the Committee for Risk Assessment shall adopt an opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health or the environment, based on its consideration of the relevant parts of the restriction dossier. This opinion shall take account of the restriction dossier prepared by the Agency at the request of the Commission or by the Member State, and the views of interested parties referred to in Article 86(9), point (a).

RAC tasks under ROHS (OSOA)

1. Article 5(4a): Prevention

‘4a. The Agency shall, after verifying the completeness of the application, request the opinion of the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d) of Regulation (EC) No 1907/2006. It shall request the opinion of the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, in the case of an application for a new exemption, or where otherwise considered appropriate.

The Committee for Socio-economic Analysis and, where relevant, the Committee for Risk Assessment:

(a)shall draw up draft opinions within 9 months of the date the application has been considered complete by the Agency under paragraph 4, point (b);

(b)shall assess whether the criteria in Article 5(1), point (a), are met and shall provide clear guidance to the Commission on granting, renewing or revoking an exemption;

(c)may request the applicant or third parties to submit, within a specified period, additional information;

(d)upon adopting the draft opinions, shall communicate those draft opinions to the applicant and shall allow the applicant the opportunity to comment within 4 weeks of the communication of the draft opinions to the applicant;

(e)shall adopt their final opinions, taking into account the comments from the applicant.

Each Committee shall take into account any information submitted by third parties in accordance with the second subparagraph, point (c).

The Agency shall send the final opinion(s) of the Committees to the Commission within 12 months from the date an application has been considered complete by the Agency.

The Agency shall identify which parts of its opinions and of any attachments thereto should be made publicly available on its website and shall make those parts publicly available on its website.

For the purpose of adopting opinions pursuant to this paragraph, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.

RAC tasks under ROHS (OSOA), part 2

2. Article 6a(5): Initiation of procedure for review and amendment of the list of restricted substances

The Agency shall consult the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, and the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d), of that Regulation. The Committees shall verify whether the restriction dossier submitted conforms to the requirements referred to in Article 6(2), third subparagraph.

Within 30 days of receipt of the restriction dossier, the respective Committee shall inform the Agency or the Member State proposing restrictions whether the dossier conforms to the requirements referred to in Article 6(2), third subparagraph. If the dossier does not conform to those requirements, the reasons shall be given to the Agency or the Member State in writing within 45 days of receipt of that dossier. The Agency or the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the Committees, otherwise the procedure under this Article shall be terminated.

3. Article 6b(1): Opinion of the Agency's Committees

Within 12 months from the date of publication referred to in Article 6a(6), the Committee for Risk Assessment shall adopt an opinion as to whether the restriction is appropriate in reducing the risk to human health or the environment, specifically by reference to the risks set out in Article 6(1), third subparagraph, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the restriction dossier prepared by the Agency at the request of the Commission or by the Member State, and the views of interested parties referred to in Article 6a(6), point (a).

SEAC tasks under REACH

1. Article 60(4), Granting of authorisations:

If an authorisation cannot be granted under paragraph 2 or for substances listed in paragraph 3, an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. This decision shall be taken after consideration of all of the following elements and ***taking into account the opinions of*** *the Committee for Risk Assessment and the* ***Committee for Socio-economic Analysis*** *referred to in Article 64(4)(a) and (b):*

(a) the risk posed by the uses of the substance, including the appropriateness and effectiveness of the risk management measures proposed;

(b) the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties;

(c) the analysis of the alternatives submitted by the applicant under Article 62(4)(e) or any substitution plan submitted by the applicant under Article 62(4)(f), and any third party contributions submitted under Article 64(2);

(d) available information on the risks to human health or the environment of any alternative substances or technologies.

2. Article 64(1): Procedure for authorisation decisions

The Agency shall acknowledge the date of receipt of the application. The Agency's Committees for Risk Assessment and ***Socio-economic Analysis*** *shall give their draft opinions within ten months of the date of receipt of the application.*

3. Article 64(3): Procedure for authorisation decisions

In preparing its opinion, ***each Committee*** *referred to in paragraph 1* ***shall first check that the application includes all the information specified in Article 62*** *that is relevant to its remit. If necessary, the Committees shall, in consultation with each other,* ***make a joint request to the applicant for additional information*** *to bring the application into conformity with the requirements of Article 62. The Committee for Socio-economic Analysis may, if it deems it necessary, require the applicant or request third parties to submit, within a specified time period, additional information on possible alternative substances or technologies. Each Committee shall also take into account any information submitted by third parties.*

SEAC tasks under REACH (part 2)

4. *Article 64(4b):* Procedure for authorisation decisions

The draft opinions shall include the following elements:(b) Committee for Socio-economic Analysis: an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application, when an application is made in accordance with Article 62 and of any third party contributions submitted under paragraph 2 of this Article.

5. *Article 64(5):* Procedure for authorisation decisions

The Agency shall send these draft opinions to the applicant *by the end of the deadline set out in paragraph 1. Within one month of receipt of the draft opinion, the applicant may provide written notice that he wishes to comment. The draft opinion shall be deemed to have been received seven days after the Agency has sent it.*
If the applicant does not wish to comment, the Agency shall send these opinions to the Commission, the Member States and the applicant, within 15 days of the end of the period within which the applicant may comment or within 15 days of receipt of notice from the applicant that he does not intend to comment.
If the applicant wishes to comment, he shall send his written argumentation to the Agency within two months of the receipt of the draft opinion. ***The Committees shall consider the comments*** *and adopt their final opinions within two months of receipt of the written argumentation, taking this argumentation into account where appropriate.* ***Within a further 15 days the Agency shall send the opinions,*** *with the written argumentation attached,* ***to the Commission, the Member States and the applicant****.*

SEAC tasks under REACH (part 3)

6. Article 69(4): Preparation of a proposal (restriction)

If a Member State considers that the manufacture, placing on the market or use of a substance on its own, in a ►M3 mixture ◄ or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed it shall notify the Agency that it proposes to prepare a dossier which conforms to the requirements of the relevant sections of Annex XV. If the substance is not on the list maintained by the Agency referred to in paragraph 5 of this Article, the Member State shall prepare a dossier which conforms to the requirements of Annex XV within 12 months of the notification to the Agency. If this dossier demonstrates that action on a Community-wide basis is necessary, beyond any measures already in place, the Member State shall submit it to the Agency in the format outlined in Annex XV, in order to initiate the restrictions process.
The Agency or Member States shall refer to any dossier, chemical safety report or risk assessment submitted to the Agency or Member State under this Regulation. The Agency or Member States shall also refer to any relevant risk assessment submitted for the purposes of other Community Regulations or Directives. To this end other bodies, such as agencies, established under Community law and carrying out a similar task shall provide information to the Agency or Member State concerned on request.
The Committee for Risk Assessment and ***the Committee for Socio-economic Analysis shall check whether the dossier submitted conforms to the requirements of Annex XV****. Within 30 days of receipt, the respective Committee shall inform the Agency or the Member State suggesting restrictions, as to whether the dossier conforms. If the dossier does not conform, the reasons shall be given to the Agency or the Member State in writing within 45 days of receipt. The Agency or the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the Committees, otherwise the procedure under this Chapter shall be terminated. The Agency shall publish without delay the intention of the Commission or of a Member State to instigate a restriction procedure for a substance and shall inform those who submitted a registration for that substance.*

SEAC tasks under REACH (part 4)

7. Article 71(1): Agency opinion: Committee for Socio-economic Analysis (restriction)

*Within 12 months of the date of publication referred to in Article 69(6), **the Committee for Socio-economic Analysis shall formulate an opinion on the suggested restrictions**, based on its consideration of the relevant parts of the dossier and the socio-economic impact. It shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account of the analyses or information according to Article 69(6)(b), if there are any. The Agency shall publish the draft opinion on its website without delay. The Agency shall invite interested parties to give their comments on the draft opinion no later than 60 days from the publication of that draft opinion.*

8. Article 76(2): Composition

*The Committees referred to in points (c), (d) and (e) of paragraph 1 (hereinafter referred to as the Committees) and the Forum **may each establish working groups.** For this purpose **they shall adopt**, in accordance with their rules of procedure, **precise arrangements** for delegating certain tasks to these working groups.*

9. Article 76(3): Composition

The Committees and the Forum may, if they consider it appropriate, seek advice on important questions of a general scientific or ethical nature from appropriate sources of expertise.

SEAC tasks under REACH (part 5)

10. Article 77(3): Tasks

The Committees shall undertake the following tasks:(a) performing the tasks allotted to them under ►M3 Titles VI to X ◄ ;(b) at the Executive Director's request, providing technical and scientific support for steps to improve cooperation between the Community, its Member States, international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on sound management of chemicals in developing countries;(c) at the Executive Director's request, drawing up an opinion on any other aspects concerning the safety of substances on their own, in ►M3 mixtures ◄ or in articles.

11. Article 85(9): Establishment of the Committees

Each Committee shall draft a proposal for its own rules of procedure, to be approved by the Management Board, within six months of the Committees first being appointed.

12. Article 110(4): Relations with relevant Community bodies

The Executive Director, having consulted the Committee on Risk Assessment, the Committee on Socio-economic Analysis and the Advisory Committee on Safety, Hygiene and Health Protection at Work, shall establish rules of procedure concerning worker protection issues. These rules of procedure shall be adopted by the Management Board, in agreement with the Commission.This Title shall not affect the competences vested in the Advisory Committee on Safety, Hygiene and Health Protection at Work and the European Agency for Health and Safety at Work.

SEAC tasks under End of life vehicles

1. Article 5(7): Requirements for substances in vehicles

At the latest nine months following the submission of the report referred to in paragraph 4 to the Commission, the Committee for **Socio-economic Analysis** of the Agency, set up pursuant to Article 76(1), point (d), of Regulation (EC) No 1907/2006, shall adopt an **opinion on the report and on the specific amendments proposed**. The Agency shall submit that opinion to the Commission without delay.

SEAC tasks under Batteries Regulation

1. Article 86(7): Restriction procedure for substances

The Committee for Risk Assessment, set up pursuant to Article 76(1)(c) of Regulation (EC) No 1907/2006, and the Committee for Socioeconomic Analysis, set up pursuant to Article 76(1)(d) of that Regulation, shall check whether the restriction dossier submitted conforms to the requirements of Annex XV to that Regulation. Within 30 days of receipt of the dossier, the respective Committee shall inform the Agency or the Member State suggesting restrictions, as to whether the dossier conforms. If the dossier does not conform, the reasons shall be given to the Agency or the Member State in writing within 45 days of receipt. The Agency or the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the respective Committee, otherwise the procedure under this Article shall be terminated.

2. Article 87(2), (4): Opinion of the Agency Committees

2. Within 15 months of the date of publication referred to in Article 86(9), the Committee for Socioeconomic Analysis shall adopt an opinion on the suggested restrictions, based on its consideration of the relevant parts of the restriction dossier and the socioeconomic impact. Prior to that, it shall prepare a draft opinion on the suggested restrictions and on the related socioeconomic impact, taking account of the analyses or information according to Article 86(9), point (b), if there are any.

4.The Committee for Socioeconomic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received by the deadline set in paragraph 3 of this Article. That opinion shall take account of the comments of interested parties submitted under Article 86(9), point (b), and paragraph 3 of this Article.

SEAC tasks under ROHS (OSOA)

1. Article 5(4a): Prevention

‘4a. The Agency shall, after verifying the completeness of the application, request the opinion of the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d) of Regulation (EC) No 1907/2006. It shall request the opinion of the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, in the case of an application for a new exemption, or where otherwise considered appropriate.

The Committee for Socio-economic Analysis and, where relevant, the Committee for Risk Assessment:

(a)shall draw up draft opinions within 9 months of the date the application has been considered complete by the Agency under paragraph 4, point (b);

(b)shall assess whether the criteria in Article 5(1), point (a), are met and shall provide clear guidance to the Commission on granting, renewing or revoking an exemption;

(c)may request the applicant or third parties to submit, within a specified period, additional information;

(d)upon adopting the draft opinions, shall communicate those draft opinions to the applicant and shall allow the applicant the opportunity to comment within 4 weeks of the communication of the draft opinions to the applicant;

(e)shall adopt their final opinions, taking into account the comments from the applicant.

Each Committee shall take into account any information submitted by third parties in accordance with the second subparagraph, point (c).

The Agency shall send the final opinion(s) of the Committees to the Commission within 12 months from the date an application has been considered complete by the Agency.

The Agency shall identify which parts of its opinions and of any attachments thereto should be made publicly available on its website and shall make those parts publicly available on its website.

For the purpose of adopting opinions pursuant to this paragraph, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.

SEAC under ROHS (OSOA)

2. Article 6b: Opinion of the Agency's Committees

Within 15 months from the date of publication referred to in Article 6a(6), the Committee for Socio-economic Analysis, shall adopt an opinion on the proposed restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. Prior to that, it shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account any existing analysis or information according to Article 6a(6), point (b).

3. Article 6b: Opinion of the Agency's Committees

The Committee for Socio-economic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received by the deadline set in paragraph 3. This opinion shall take into account the comments of interested parties submitted under Article 6a(6), point (a), and paragraph 3 of this Article.

Thank you