How case owners can contribute in RAC and SEAC

Tenth Stakeholders' Day

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RAC and SEAC composition

- Capacity 62 members (incl. 6 EEAs)
  - RAC currently has 44 members (incl. 2 EEAs)
  - SEAC currently has 37 members (no EEAs)
- Members are nominated by the Member States but appointed by the Management Board of ECHA in their individual capacity
- Members expected to provide at least 50% of their time to RAC with support from MS

Independent Scientific Committees

Working practices

- The Committee appoints a (co-)rapporteur to each case to draft the opinion
- Draft opinions are scrutinised during members consultations (written) between meetings
- The results of the public consultation are taken into account
- Agreement is by consensus in plenary

Four meetings a year – much of the work of scrutiny is done in between

Regulatory processes covered

RAC & SEAC

- REACH (EC) 1907/2006
  - Authorisations
  - Restrictions
  - Article 77(3)c

    (at the request of the Executive Director)

RAC

Classification, Labelling & Packaging, (EC) 1272/2008

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Process	No. of adopted opinions	
	RAC	SEAC
CLP	174	-
Authorisations	38	38
Restrictions	14	13
Art. 77(3)c	9	-

Stakeholder access

- RAC/SEAC procedures do not make provisions for ‘case owners’ as such
- Stakeholders may be granted observer status at meetings
  - RAC/SEAC Rules of Procedure Article 6(8)
- Status approved by the Committee on an annual basis
- ECHA Code of conduct for observers from stakeholder organisations applies

There are several meaningful ways to participate

CLP and Restrictions 1

- An Annex XV proposal is submitted by an MS
- The dossier submitter is sometimes present (more usually through Webex)
- Stakeholders may request ECHA to invite experts to accompany them to RAC and SEAC meetings
- Stakeholder observer experts usually represent lead registrants, or patent/licence owners
- Committee practice is to invite these observer experts to intervene on the science of the case

Industry has played a very useful role in opinion making, in particular for CLP and Restrictions

CLP and Restrictions 2

- Annex XV proposals are subject to public consultation:
  - **CLP:** a 6-week duration in an 18 month process
  - **Restrictions:** 6 months in a 9-12 month process (RAC & SEAC resp.)
- Primary opportunity for parties to provide comments on the DS proposal and contribute additional data
- After the close of the public consultation, submissions will generally not be taken into account

Check the ECHA registry of intentions – this provides a clear early warning

Authorisation 1

- An application for authorisation of an Annex XIV substance is submitted by a manufacturer, importer, or a downstream user
- Once the invoice is paid, the clock starts
- Applicants are not invited to attend RAC or SEAC
- Stakeholder observers present but with limited speaking rights (no STO experts)
- Applicants receive a set of detailed written questions from the rapporteurs

Applicants have an opportunity to respond

Authorisation 2

- Applicants may be invited to a 'trialogue' at ECHA to discuss these questions
  - Third parties, including competitors may also be invited
- The trialogue is held at the discretion of the rapporteurs - usually reserved for complex cases
- In this way, the applicant has a further opportunity to present their case

There is no substitute for a well-written application (CSA, assessment of alternatives and SEA)

Authorisation 3

- RAC provides DNEL and dose-response data for Annex XIV substances
- 'Reference value' notes are agreed by RAC and published on the ECHA website
- A large majority of the applications to date have used the RAC reference values, saving time for:
  - the rapporteurs in preparing the opinion
  - the Committee in plenary
  - the applicant in preparing the CSR

Stakeholder observer experts have contributed to developing reference values in the Committee

Key messages

- RAC and SEAC: independent scientific Committees responsible for parts of REACH and CLP
- Committee's work goes on between meetings – efficient, fast-moving process
- Public consultation is the main opportunity for parties to contribute in CLP and Restrictions
- *Stakeholder observer experts* may provide valuable scientific contributions in the Committees under certain circumstances
  - Authorisation applicants have specific opportunities to respond to Committee requests

Thank you

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