

Final Draft Agenda
44th meeting of the Committee for Socio-economic Analysis

16 - 20 September 2019

ECHA Conference Centre (Annankatu 18, Helsinki)

Monday 16 September starts at 14.00
Friday 20 September ends at 12.00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

SEAC/A/44/2019
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Report from other ECHA bodies and activities

- a) Report on SEAC-43 action points, written procedures and update on other ECHA bodies

For information

Item 5 – Restrictions

5.1 Restriction Annex XV dossiers

- a) Conformity check and key issues discussion
- 1) Calcium cyanamide in fertilisers

For discussion and agreement

- b) Opinion development

- 1) Skin sensitisers in textile – first draft opinion

2) Perfluorohexane-1-sulphonic acid, its salts and related substances – first draft opinion

3) Siloxanes (D4, D5 and D6) – second draft opinion

4) Formaldehyde – second draft opinion

5) Microplastics – second draft opinion

6) Five cobalt salts – third draft opinion

For discussion

7) *N,N*-dimethylformamide – third draft opinion

For discussion and agreement

8) PAHs in granules and mulches used as infill material – draft final opinion

For discussion and adoption

5.2 Appointment of (co-)rapporteurs for restriction dossiers

***SEAC/44/2019/01
(restricted document)***

Item 6 – Authorisation

6.1 General authorisation issues

a) Update on incoming/future applications

b) Production and (re-)approval of medicinal products: presentation by an expert of a national authority

For information

6.2 Authorisation applications

a) Discussion on key issues

1) 27 applications for authorisation from May 2019 submission window (OPE/NPE, CTPht, Cr(VI))

For discussion

b) Agreement on draft opinion

1) CT_TES (1 use)

2) SC_Ariston (1 use)

3) SD_Bussi (1 use)

4) CTPht_Ariane (1 use)

- 5) OPE_Boehringer (1 use)
- 6) OPE_Ortho (2 uses)
- 7) OPE_Stago (2 uses)
- 8) OPE_BioMarin (2 uses)
- 9) OPE_Sebia (3 uses)
- 10) NPE_Sebia (1 use)
- 11) OPE_bioMerieux (3 uses)

For discussion and agreement

6.3 Appointment of (co-)rapporteurs for authorisation applications (closed session)

**SEAC/44/2019/02
(restricted room document)**

Item 7 – AOB

- a) Update of the work plan
- b) Study for the development of an evidence-based approach as support to regulators when assessing how to manage the presence of substances of concern in recycled materials (presentation by RIVM of the final results)

For information

Item 8 – Action points and main conclusions of SEAC-44

Table with Conclusions and Action points from SEAC-44

For adoption