RAC/M/51/2019

Final

14 February 2020

Minutes of the 51st Meeting

of the Committee for Risk Assessment (RAC 51)

Monday 25, 14.00 to Thursday 28 November, 13.00
and
Tuesday 3, 09.00 to Thursday 5 December, 13.00

Summary Record of the Proceedings, and Conclusions and action points

Chairman's opening address

The chairman reflected on the following topics in his opening address:

- A new style of minute preparation (the summary record section) in a much shorter format and with the possibility of adoption at the end of (each week of) the current meeting, this latter to be put to the 56th ECHA Management Board meeting on 12 December 2019.
- Revision of the process for preparing restriction opinions for Committee to allow for a smoother preparation for plenary meetings for members, rapporteurs and secretariat.
- The report of the RAC AfA working group meeting in October was brought to member's attention, as was a new document collecting learnings from the evaluation of the first AfA applications on OP/NPnEO.
- The imminent move of the Agency to the new location at Telakkakatu 6 was outlined.

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/51/2019**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-51 minutes.
4. Appointment of (co-)rapporteurs	
a) Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits The Secretariat collected the names of volunteers for rapporteurships for CLH dossiers, authorisation applications and OELs, as stated in the restricted room document. The Committee agreed upon the proposed appointments of the Rapporteurs for the intentions and/or newly submitted CLH dossiers, as well as the pool for the applications for Authorisation and OELs.	-

5. Report from other ECHA bodies and activities	
a) Report on RAC 50 action points, written procedures and update on other ECHA bodies The Chairman informed the Committee that the action points from the previous meeting RAC-50, pending publications of some CLH opinions, were nearing completion. The summary of all substances related written procedures, calls for expression of interests in (co-)rapporteurship and written procedures for appointments of rapporteurs, and adopted opinions, is provided in the room document on administrative issues (RAC/51/2019/01) (see Annex IV). **SECR** presented document **RAC/51/2019/01.**	**SECR** to upload the document to the CIRCABC non-confidential website.
b) RAC work plan for all processes **SECR** presented the RAC work plan for quarter one to three 2020.	-
c) Revised rules for procedure RAC agreed on the revised Rules of Procedure of the Committee for Risk Assessment. (**RAC/51/2019/02**).	**SECR** to inform the Management Board on the agreement of RAC on the proposed revised Rules of Procedures.
6. Health based exposure limits at the workplace	
a) Discussion on key issues (prior to the availability of a draft opinion)	
1. Lead and its compounds	
The Chairman welcomed the expert accompanying the regular Eurometaux stakeholder observer as well as the two occasional stakeholders. He reported that the request to ECHA to evaluate limit values for lead and its compounds at the workplace, in accordance with Chemical Agents Directive, was submitted by DG EMPL via Service Level Agreement in March 2019 with a deadline of 18 months to September 2020. A call for evidence in the preparatory phase inviting interested parties to submit comments and evidence on the subject took place from 17 April to 30 June 2019. The ECHA scientific report was launched for a two month consultation from 17 October to 16 December 2019. In parallel, a RAC consultation was launched from 28 October to 2 December 2019.	

RAC discussed the key issues of ECHA scientific report for evaluation of limit values for lead and its compounds at the workplace. • There was general support to the approach of deriving a biological limit value for lead concentrations in blood as the primary limit value and to also if feasible to set an air limit value; • Neurotoxicity was considered to be the most sensitive endpoint; • Other effects should also be considered (e.g. renal, cardiovascular and haematological); • Organic compounds might require more detailed consideration; • Reducing the risk for women of childbearing age at the workplace also needs further consideration.	Rapporteurs to prepare the draft opinion taking into account RAC-51 discussions and RAC consultation and comments received in the Public Consultation.
The expert accompanying the regular Eurometaux stakeholder observer commented on the importance of thoroughly evaluating the primary literature for quality and the design of human epidemiology studies that will form the basis for setting the blood limit values and the air limit values. One of the occasional stakeholders commented on the risk for women of childbearing age.	
2. Diisocyanates	
The Chairman welcomed the expert accompanying the regular Cefic stakeholder observer, the expert accompanying the regular EuPC stakeholder observer and two occasional stakeholders. The Chairman reported that the request to ECHA to evaluate limit values for diisocyanates at the workplace, in accordance with Chemical Agents Directive, was submitted by DG EMPL via Service Level Agreement in March 2019 with a deadline of 18 months (September 2020). A call for evidence in the preparatory phase inviting interested parties to submit comments and evidence on the subject took place from 17 April to 30 June 2019. The ECHA scientific report was launched for a two month public consultation from 17 October to 16 December 2019. In parallel a RAC consultation was launched from 28 October to 2 December 2019.	
RAC discussed the key issues of the ECHA scientific report for evaluation of limit values for diisocyanates at the workplace. • There was general support for a non-threshold approach and to deriving exposure response relations based on the 'NCO-group' approach; • Specific endpoints causing respiratory effects were seen as the most relevant endpoints;	Rapporteurs to prepare the draft opinion taking into account RAC-51 discussions and RAC consultation and comments received in the Public Consultation.

• A biological guidance value could possibly be set recognising analytical considerations; • A short term exposure limit should be reconsidered by taking short term human studies on board.	
The expert accompanying the regular CEFIC stakeholder observer commented on using NCO group approach and on the possibility to define a threshold.	

7. Harmonised classification and labelling (CLH)

7.1 General CLH issues

The Chairman informed the Committee that the action points from the previous meeting RAC-50, pending publications of some CLH opinions, were nearing completion. The summary of all substance - related written procedures, calls for expression of interests in (co-)rapporteurship and written procedures for appointments of rapporteurs, and adopted opinions, is provided in the room document on administrative issues (RAC/51/2019/01) (see Annex IV).

a) Corrigendum to the adopted opinion on L-(+)- lactic acid

The Secretariat informed the Committee that in the context of the Caracal discussions and following commenting round on the draft 15th ATP to the CLP Regulation (Adaptation to technical and scientific progress, containing RAC opinions from 2018), comments were raised by some stakeholders and Member State Competent Authorities in relation to the adopted opinion on L-(+)-lactic acid, more specifically to the generic concentration limits (GCL) for skin corrosion / irritation and serious eye damage / eye irritation.

During the finalisation of the opinion, the conclusion concerning severe eye damage was erroneously modified by ECHA, giving the impression that RAC did conclude that the 1% GCL applies to mixtures containing L-(+)-lactic acid. The reference to the 1% GCL was intended as a statement of fact (as was the case in the Section on skin corrosion/ irritation).

References to GCLs are not usually included in the RAC opinion. ECHA therefore proposed to remove the pertinent text from the RAC opinion and to issue a corrigendum to this end.

RAC agreed to this proposal.

b) Physical hazards

The Secretariat informed the Committee about the recent discussions at CARACAL for the 15th ATP to the CLP Regulation (RAC 2018 opinions) revealing that there needs to be a more detailed assessment of physical hazards in the CLH dossiers.

To this end, the Secretariat had compiled a paper (CLP / Physical Hazards Note, *room document*) aiming to highlight the differences in the preferred experimental methods to assess the physical properties in e.g. the REACH Regulation versus those necessary for classification according to CLP. The paper further proposes the way forward to check that the physical hazards have been assessed appropriately and to limit the likelihood of incorrect or unclear assessment for the CLH dossiers that are already in the CLH process.

The ECPA Regular Stakeholder Observer noted that for plant protection products that are for renewal pursuant to the plant protection product Regulation (EC) 1107/2009, the physical hazards are usually assessed according to the 'old' standards thus would not comply with this most recent

approach. He further confirmed that internal discussions were ongoing within ECPA with the aim to address this issue and he would provide further details on this issue and the outcome of the discussions once these were available.

7.2 CLH dossiers

A. Substances with hazard classes for agreement by A-listing following the usual scrutiny but without plenary debate

- 24-epibrassinolide: physical hazards (explosives, flammable solids, pyrophoric solids, self-heating substances, oxidising solids), acute toxicity, skin corrosion / irritation, serious eye damage / eye irritation, STOT SE, STOT RE
- carbendazim (ISO): physical hazards (explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids), skin sensitisation, hazards to the aquatic environment
- silanamine: physical hazards (explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance or mixture which in contact with water emits flammable gas, oxidising solid, substance or mixture corrosive to metals), acute toxicity (oral and dermal routes of exposure), skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, hazards to the aquatic environment
- trinexapac-ethyl (ISO): physical hazards (explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance or mixture which in contact with water emits flammable gas, oxidising liquid, oxidising solid), acute toxicity, STOT SE, serious eye damage/irritation, germ cell mutagenicity
- 1,4-dimethylnaphthalene: physical hazards (explosive, flammable gas, flammable liquid, self-reactive substance or mixture, pyrophoric liquid, substance or mixture which in contact with water emits flammable gas, oxidising liquid), acute toxicity (dermal and inhalation routes of exposure), skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, STOT SE, STOT RE, hazards to the aquatic environment
- imazamox (ISO): hazards to the aquatic environment
- 3-methylpyrazole: acute oral toxicity, skin corrosion / irritation, serious eye damage / eye irritation

B. Substances with hazard classes for agreement in plenary session

1. 24-epibrassinolide
2. acetamiprid (ISO) (hazards to the aquatic environment only)
3. cypermethrin (ISO)
4. tetrafluoroethylene
5. thiamethoxam (ISO)
6. silanamine
7. trinexapac-ethyl (ISO) (human health hazards only)
8. 1,4-dimethylnaphthalene
9. imazamox (ISO)
10. 3-methylpyrazole

- **carbendazim (ISO)**

Carbendazim (ISO) is an active substance in plant protection and biocidal products used in film preservatives, fibre, leather, rubber and polymerised materials preservatives and in construction material preservatives. It has an existing entry in Annex VI to the CLP Regulation for the following hazards: Muta. 1B; H340, Repr. 1B; H360FD, Aquatic Acute 1; H400, Aquatic Chronic 1; H410. Legal deadline for the adoption of an opinion is 16 May 2020.

The Dossier Submitter (DE) proposed to add the following classifications: Skin Sens. 1; H317 and M-factors to the existing environmental classifications (Aquatic Acute 1; H400, M=10 and Aquatic Chronic 1; H410, M=10).

Selected physical hazards (explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance or mixture which in contact with water emits flammable gas, oxidising solid, organic peroxide), skin sensitisation and hazards to the aquatic environment were open for comments during the public consultation.

Following the detailed scrutiny of the draft opinion during the RAC consultation, no further discussion was deemed necessary at the plenary.

The Committee agreed to the proposal by the DS to classify carbendazim (ISO) as listed below.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Skin Sens. 1; H317, Aquatic Acute 1; H400, M=10, Aquatic Chronic 1; H410, M=10]	**Rapporteurs** to revise the opinion based on the RAC comments and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

No experts accompanying the RAC Regular Stakeholder Observers were present.

1. **24-epibrassinolide**

24-epibrassinolide is an active substance in plant protection products used in agriculture (viticulture, arable crops and vegetable production). It has no existing Annex VI entry. Legal deadline for the adoption of an opinion is 11 July 2020.

The Dossier Submitter (AT) proposed to classify the substance for hazards to the aquatic environment (Aquatic Chronic 4; H413).

Selected physical hazards (explosives, flammable solids, pyrophoric solids, self-heating substances, oxidising solids), human health hazards (except respiratory sensitisation and aspiration hazard) and hazards to the aquatic environment were open for comments during the public consultation.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Aquatic Chronic 4; H413]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.

	SECR to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
The ECPA Regular Stakeholder Observer addressed the issue of limited data in the CLH report on this substance raised by several RAC Members and explained that 24-epibrassinolide belongs to a group of so-called low risk active substances pursuant to Article 22 of Regulation (EC) 1107/2009 (Plant Protection Products Regulation).	
2. acetamiprid (ISO)	
The Chairman welcomed the expert accompanying the ECPA Regular Stakeholder Observer and reported that acetamiprid (ISO) is an active substance in plant protection products used as an insecticide to control herbivorous (sucking and biting) insects. It has an existing entry in Annex VI to the CLP Regulation as Acute Tox. 4*; H302 (minimum classification) and Aquatic Chronic 3; H412. The legal deadline for the adoption of an opinion is 23 April 2020. The Dossier Submitter (NL) proposed to modify/add the following aquatic hazard classes: Aquatic Acute 1; H400 M=10 and Aquatic Chronic 1; H410 M=100. For human health the Dossier Submitter proposed to modify/add the classification to Acute Tox. 3; H301, Carc. 2; H351 and Repr. 2; H361d. Acute oral toxicity, carcinogenicity, toxicity to reproduction and hazards to the aquatic environment were open for comments during the public consultation. The human health hazards for this substance will be discussed at RAC 52 / March 2020.	
RAC agreed on the harmonised classification and labelling as indicated in Table 2 below. [Aquatic Acute 1; H400, M=10 and Aquatic Chronic 1; H410, M=10]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the environmental part of the opinion in consultation with the Rapporteurs. **Rapp** to draft the human health part of the opinion and provide it for the RAC consultation prior to RAC 52. **SECR** to launch the RAC consultation on the human health part of the ODD and to schedule the dossier for the adoption at RAC 52.
The expert accompanying the ECPA Regular Stakeholder Observer did not intervene during the discussion.	
3. cypermethrin (ISO)	
The Chairman welcomed the expert accompanying the ECPA Regular Stakeholder Observer and reported that cypermethrin (ISO) is an active substance in biocidal products used as an insecticide. It has an existing entry in Annex VI to the CLP Regulation for acute oral and inhalation toxicity	

(Acute Tox. 4*; H302 and Acute Tox. 4*; H332 (minimum classifications)), as STOT SE 3; H335 and for hazards to the aquatic environment (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410). Legal deadline for the adoption of an opinion is 14 May 2020.

The Dossier Submitter (BE) proposed to confirm Acute Tox. 4; H302 and Acute Tox. 4; H332, and to add STOT RE 2; H373 (nervous system) and M-factors for the aquatic hazards (Aquatic Acute 1; H400, M=100 and Aquatic Chronic 1; H410, M=1000).

Acute toxicity, specific target organ toxicity (repeated exposure) and hazards to the aquatic environment were open for comments during the public consultation.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [STOT RE 2; H373 (nervous system), Acute Tox. 4; H302, ATE(oral) = 500 mg/kg, Acute Tox. 4, H332, ATE(inhalation) = 3,3 mg/L, Aquatic Acute 1; H400, M=100 000, Aquatic Chronic 1; H410, M=100 000]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

The expert accompanying the ECPA Regular Stakeholder Observer clarified that the existing classification for respiratory irritation (STOT SE 3 – not open for public consultation in the CLH report) was triggered by human experience from using cypermethrin in ventilation systems in the United States.

The expert further intervened during the discussion on degradability of the compound.

4. tetrafluoroethylene

The Chairman welcomed the expert accompanying the Cefic regular stakeholder observer and reported that tetrafluoroethylene is an industrial chemical used primarily in the manufacture of polymers. It has no existing entry in Annex VI to the CLP Regulation. The legal deadline for the adoption of an opinion is 30 May 2020.

The Dossier Submitter (IE) proposed to classify the substance for carcinogenicity (Carc. 1B; H350).

Carcinogenicity was the only hazard open for comments during the public consultation.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 1B; H350]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

The expert accompanying the Cefic regular stakeholder observer agreed to the proposed classification, but expressed the preference for specifying the route of exposure and for setting a specific concentration limit.

5. thiamethoxam (ISO)

The Chairman welcomed the expert accompanying the ECPA Regular Stakeholder Observer and reported that thiamethoxam (ISO) is an active substance in plant protection products used as an insecticide. It has an existing entry in Annex VI to the CLP Regulation for acute oral toxicity (Acute Tox. 4*; H302 (minimum classification) and for hazards to the aquatic environment (Aquatic Acute 1; H400, M=10 and Aquatic Chronic 1; H410). Legal deadline for the adoption of an opinion is 12 June 2020.

The Dossier Submitter (FR) proposed to classify the substance as Flam. Sol. 1; H228, Acute Tox. 4; H302, (ATE (oral) = 800 mg/kg bw), Repr. 2; H361 and to add an M-factor to aquatic chronic hazard (Aquatic Acute 1; H400, M = 10 and Aquatic Chronic 1; H410, M = 10).

Physical hazard (flammable solid), acute toxicity, toxicity to reproduction, and hazards to the aquatic environment were open for comments during the public consultation.

RAC adopted with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 2; H361fd, Acute Tox. 4; H302, ATE = 780 mg/kg bw, Aquatic Acute 1; H400, M=10, Aquatic Chronic 1; H410, M=10]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

The expert accompanying the ECPA Regular Stakeholder Observer did not intervene during the discussion.

6. silanamine

Silanamine is an active substance in biocidal products used as an insecticide, acaricide and in products to control other arthropods. It has no existing entry in Annex VI to the CLP Regulation. Legal deadline for the adoption of an opinion is 17 June 2020.

The Dossier Submitter (FR) proposed to classify the substance for repeated dose toxicity (STOT RE 2; H373 (lungs) (inhalation)) and to add the supplemental hazard statement EUH066 (repeated exposure may cause skin dryness or cracking).

Selected physical hazards (explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance or mixture which in contact with water emits flammable gas, oxidising solid, substance or mixture corrosive to metals), acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, toxicity to reproduction, specific target organ toxicity - repeated exposure and hazards to the aquatic environment were open for comments during the public consultation.

RAC adopted by simple majority the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 2; H330, ATE(inhalation) = 0,45 mg/L, STOT RE 2; H373 (lungs) (inhalation), additional labelling EUH066]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to launch a targeted public consultation on the data not included in the CLH report that lead to the conclusion on the classification on acute toxicity by inhalation. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
No experts accompanying RAC Regular Stakeholder Observers were present. There was no intervention from the Stakeholder Observers during the discussion.	

7. trinexapac-ethyl (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that trinexapac-ethyl (ISO) is an active substance used in plant protection products used as plant growth regulator. It has no existing entry in Annex VI to the CLP Regulation. The legal deadline for the adoption of an opinion is 14 March 2020.

The Dossier Submitter (LT) proposed to classify the substance as Skin Sens 1B; H317 and for chronic aquatic hazards - Aquatic Chronic 1, H410, M-factor=1.

Selected physical hazards (explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance or mixture which in contact with water emits flammable gas, oxidising liquid, oxidising solid), human health and environmental hazards (with exception of aspiration hazard and hazardous to the ozone layer) were open for comments during the public consultation.

At RAC 50, the Committee agreed on hazards to the aquatic environment (Aquatic Chronic 1, H410, M=1) in line with the DS proposal.

RAC adopted by simple majority the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Skin Sens. 1B; H317, STOT RE 2; H373 (gastrointestinal tract), Aquatic Chronic 1, H410, M=1]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
The expert accompanying the ECPA Regular Stakeholder Observer commented on skin sensitisation / amount of an impurity used in the compound. The ECPA expert further intervened during the	

discussion on repeated dose toxicity in relation to the details of a rabbit developmental toxicity study.

8. 1,4-dimethylnaphthalene

1,4-dimethylnaphthalene is an active substance in plant protection products used as a dormancy enhancer in potatoes during storage. It has no existing entry in Annex VI to the CLP Regulation. The legal deadline for the adoption of an opinion is 9 August 2020.

The Dossier Submitter (NL) proposed to classify for the following hazards: Eye Irrit. 2; H319, Asp. Tox. 1; H304, Aquatic Acute 1; H400, M=1 and Aquatic Chronic 2; H411.

Selected physical hazards (explosive, flammable gas, flammable liquid, self-reactive substance or mixture, pyrophoric liquid, substance or mixture which in contact with water emits flammable gas, oxidising liquid), acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, carcinogenicity, toxicity to reproduction, STOT SE, STOT RE, aspiration hazard and hazards to the aquatic environment were open for comments during the public consultation.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4; H302, ATE of 1300 mg/kg, Eye Irrit. 2; H319; Asp. Tox. 1; H304, Aquatic Acute 1; H400, M=1 and Aquatic Chronic 3; H412]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

No experts accompanying RAC Regular Stakeholder Observers were present. There was no intervention from the RAC Regular Stakeholder Observers during the discussion.

9. imazamox (ISO)

The Chairman welcomed the expert accompanying the ECPA Regular Stakeholder Observer and reported that imazamox (ISO) is an active substance in plant protection products used as a herbicide. It has an existing entry in Annex VI to the CLP Regulation for hazards to the aquatic environment (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410). The legal deadline for the adoption of an opinion is 8 August 2020.

The Dossier Submitter (FR) proposed to add classification for toxicity to reproduction (Repr. 2; H361d) and to add M-factors of 10 for both environmental hazards.

Toxicity to reproduction and hazards to the aquatic environment were open for comments during the public consultation.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 2; H361d, Aquatic Acute 1; H400, M=10, Aquatic Chronic 1; H410, M=10]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.

	SECR to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
The expert accompanying the ECPA Regular Stakeholder Observer provided some details on individual animal data in the rabbit developmental toxicity study and in relation to the historical control data sets provided by Industry during the public consultation on the CLH report.	
10. 3-methylpyrazole	
3-methylpyrazole is an industrial chemical used in fertilisers. It has no existing entry in Annex VI to the CLP Regulation. The legal deadline for the adoption of an opinion is 15 August 2020. The Dossier Submitter (BE) proposed to classify the substance as follows: Acute Tox. 4; H302 (ATE (oral) = 500 mg/kg bw), Skin Corr. 1; H314, Eye Dam. 1; H318, STOT RE 1; H372 (lungs), Repr. 1B; H360D. Acute toxicity (oral, inhalation), skin corrosion/irritation, serious eye damage/eye irritation, STOT RE and toxicity to reproduction were open for comments during the public consultation.	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360D, Acute Tox. 4; H302 (ATE (oral) = 500 mg/kg bw), Skin Corr. 1; H314, Eye Dam. 1; H318, STOT RE 2; H373 (lungs)]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
No experts accompanying RAC Regular Stakeholder Observers were present. There was no intervention from the Regular Stakeholder Observers during the discussion.	
8. Restrictions	
8.1 General restriction issues	
a) Report from the Restrictions Efficiency Task Force	**RAC** took note of the report from the Restrictions Task Force provided by the SECR.
8.2 Restriction Annex XV dossiers	
a) Opinion development	
1. Calcium cyanamide in fertilisers	
The Chairman welcomed the Dossier Submitter's representatives from ECHA and an expert accompanying the Cefic regular stakeholder observer. He informed the participants that the	

restriction dossier had been submitted in July 2019 and concerns the placing on the market of calcium cyanamide used as a fertiliser.	
The rapporteurs presented and RAC discussed the first draft opinion. RAC agreed that the scope of the proposal is clear and that the targeting of the restriction is appropriate. The Rapporteurs were asked to complete the evaluation of the mesocosm study and the terrestrial field study and take them into account in their evaluation of the aquatic and terrestrial predicted no effect concentrations. The Rapporteurs were asked to carefully evaluate the modelling scenarios for exposure assessment.	**SECR** to launch written consultation on the first draft opinion. **Rapporteurs** to prepare the second draft opinion, taking into account RAC-51 discussions and the RAC written consultation, by end of January 2020.
The expert accompanying the regular Cefic stakeholder observer commented on the hazard and exposure assessment.	
2. Skin sensitisers in textiles	
The Chairman welcomed the Dossier Submitter's representatives from France and Sweden, two occasional stakeholder observers. He informed the participants that the restriction dossier had been submitted in April 2019 and proposes to restrict skin sensitising substances in finished textile, leather, hide and fur articles.	
Rapporteurs presented and RAC discussed the second draft opinion. RAC agreed to include all clothing and footwear in the scope of the Restriction (without specifying the material), as proposed by the Dossier Submitter and supported by Rapporteurs. RAC supported the inclusion of textile, leather, hide and fur articles, other than clothing, that come into contact with the skin under normal or reasonably foreseeable conditions of use to an extent similar to clothing. RAC supported the inclusion of disposable textiles in the scope of the restriction and recommended to include all parts of multilayer disposable textiles in the scope of the restriction. RAC agreed not to support the inclusion of articles covered by EU Regulation 1935/2004 (Food Contact Material Regulation) into the scope of the restriction. RAC provisionally agreed with the elicitation thresholds for risk assessment as proposed by the Rapporteurs (except for Disperse Blue 124, where	**Rapporteurs** to prepare the third draft opinion, taking into account RAC-51 discussions, by mid-December 2019 (for the RAC written consultation). **Rapporteurs** to prepare the fourth draft opinion, taking into account RAC-51 discussions, the RAC consultation and the results of the public consultation, by early February 2020.

the Rapporteurs were asked to review the data in the CLP dossier). RAC provisionally agreed with exposure assessment as proposed by the Rapporteurs.	
The Commission observer, the EDANA occasional stakeholder observer, the Euratex occasional stakeholder observer and the ClientEarth regular stakeholder observer commented on the scope of the restriction. The expert accompanying the Euratex occasional stakeholder observer commented on elicitation thresholds. The EDANA occasional stakeholder observer commented on exposure parameters, migration factors and risk characterisation.	
3. Perfluorohexane-1-sulphhonic acid, its salts and related substances	
The Chairman welcomed the Dossier Submitter's representatives from Norway (following via WebEx), the SEAC Rapporteur and stakeholder observers. He informed the participants that the restriction dossier had been submitted in April 2019 and to restrict the manufacture, use and placing on the market of PFHxS, its salts and related substances as substances, constituents of other substances, mixtures and articles or parts thereof. The restriction proposal aims at reducing the emissions of PFHxS, its salts and their related substances to the environment and to human exposure to a minimum (the main potential exposure pathways are intake via food and drinking water and through exposure to house dust).	
Rapporteurs presented the state of play on the opinion development and the results of the public consultation so far.	**Rapporteurs** to prepare the third draft opinion, taking into account RAC-51 discussions and the results of the public consultation, by early 2020.
The Commission observer commented on the derogations.	
4. Microplastics	
The Chairman welcomed the Dossier Submitter's representatives from ECHA, the SEAC Rapporteur (following via WebEx) and experts accompanying the regular ECPA, EEB, Eurometaux, Cefic and ClientEarth stakeholder observers, as well as three occasional stakeholder observers together with their accompanying experts. He informed the participants that the restriction dossier had been submitted in January 2019. In addition, Sweden (KemI) collaborated with ECHA in preparation of the dossier. The proposal aims at restricting the use of intentionally added microplastic particles to consumer or professional use products of any kind.	
The rapporteurs presented and RAC discussed the fourth draft opinion. <u>Scope of the restriction</u> RAC agreed to define a concentration limit of 0.01% w/w for all the uses.	**RAC members** to provide comments via written consultation on the fourth draft opinion by 13 December 2019. **Rapporteurs** to prepare the fifth draft opinion, taking into account RAC-51

RAC agreed to define microbeads as a microplastic used in a mixture as an abrasive. Release characterisation RAC agreed with the microplastics use and release characterisation provided. In particular, RAC agreed with the characterisation of the: • Down-the-drain pathway (with some uncertainties) • Municipal solid waste (bin/trash) pathway • Direct release to the environment pathway • Polymeric infill material releases pathway (with some uncertainties) Risk management RAC agreed with the three risk management components proposed (i.e. a complete ban, instructions for use requirements, reporting requirements). Subject to more detailed discussions on instructions for use and reporting at the next meeting. Derogations RAC agreed with derogation 3a, for natural polymers that have not been chemically modified. RAC agreed that biodegradable microplastics do not contribute to the microplastics concern and that derogation 3b (biodegradable polymers) is needed.	discussions and the RAC written consultation, by early February 2020.
The expert accompanying the regular Cefic stakeholder observer commented on the definition of 'solid' used in the proposed restriction. The experts accompanying the regular EEB and occasional EDANA stakeholder observers commented on the uncertainties in the release estimates. The Commission observer recalled the complexity of the proposed restriction and the need to properly reflect relevant arguments to support the scientific validity of the analysis in the opinion. The expert accompanying the regular Cefic stakeholder observer commented on the reporting requirement. The regular EEB stakeholder observer noted that the 4th DO for discussion during this meeting had not been provided to stakeholders. She asked for all documents and presentation to be shared before the discussions in order to enable stakeholders to better contribute. The expert accompanying the regular EEB stakeholder observer commented on the derogations.	
5. Formaldehyde and formaldehyde releasers	
The Chairman welcomed the Dossier Submitter's representatives from ECHA and expert accompanying the regular Cefic stakeholder observer. He informed the participants that the restriction dossier had been submitted in January 2019 and proposes to restrict the placing on the	

market of articles releasing formaldehyde at concentrations greater than or equal to 0.124 mg/m^3 as measured in accordance with the conditions specified in the restriction proposal.	
The rapporteurs presented and RAC discussed the third/fourth draft opinion. RAC agreed that there is no identified risk in aircraft cabins, and therefore they should be excluded from the restriction. RAC considered an emission limit of 0.05 mg/(m^2h) for building interiors and 0.05 mg/m^3 for vehicle interiors.	**RAC members** to provide comments via written consultation on the third draft opinion by 12 December 2019. The **Secretariat** to organise an open rapporteurs' dialogue (face-to-face) in early February 2020. **Rapporteurs** to prepare the fifth draft opinion, taking into account RAC-51 discussions and the RAC written consultation, as well as outcome of the dialogue, by early February 2020.
The Commission observer commented on the scope and the emission limit value. The expert accompanying the regular Cefic stakeholder observer commented on the emission limit value.	
6. Cobalt salts	
The Chairman welcomed the Dossier Submitter's representatives from ECHA, the SEAC Rapporteurs (following via WebEx), experts accompanying the regular Eurometaux and Cefic stakeholder observers, as well as one occasional stakeholder observer. He informed the participants that the restriction dossier had been submitted in October 2018 and proposes to restrict the placing on the market, manufacture and use of five cobalt salts (cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt diacetate) as substances on their own or in mixtures in a concentration equal or above 0.01% by weight in industrial and professional applications.	
The rapporteurs presented and RAC discussed the sixth draft opinion. RAC agreed to support the restriction for the five cobalt salts, as proposed by the Rapporteurs, and to recommend the Commission to consider a Binding Occupational Exposure Limit for cobalt and all its compounds.	**Rapporteurs,** together with **SECR**, to make the final editorial changes (as discussed during RAC-51) to the draft RAC opinion. **SECR** to organise the written consultation on the final draft RAC opinion. **SECR** to organise the written procedure for the adoption of the RAC opinion (lasting for 5 calendar days based on Art 20(2) of the RAC RoPs). <u>After the adoption</u>: **Rapporteurs**, together with **SECR**, to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC.

The expert accompanying the regular Cefic stakeholder observer commented on the practicality and monitorability of the proposed restriction. The expert accompanying the regular Eurometaux stakeholder observer commented on the future update of the ISO standard.	
7. D4/D5/D6	
The Chairman welcomed the Dossier Submitter's representatives from ECHA, the SEAC Rapporteurs (following via WebEx), expert accompanying the regular Cefic stakeholder observer, as well as one occasional stakeholder observer. He informed the participants that the restriction dossier had been submitted in January 2019 and proposes to restrict placing on the market of D4, D5 and D6 as substances, as constituents of other substances, or in mixtures in a concentration equal to or greater than 0.1% w/w of each substance.	
Rapporteurs presented and RAC discussed the updated third draft opinion. **RAC adopted the opinion on this restriction proposal by consensus.**	**Rapporteurs** to make final editorial changes (as discussed during RAC-51) to the adopted RAC opinion. **Rapporteurs**, together with **SECR**, to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC.
The expert accompanying the regular Cefic stakeholder observer commented on modelling. The occasional stakeholder observer as well as the COM observer commented on derogations.	
9. Authorisation	
9.1 General authorisation issues	
a) Update on incoming/future applications	
ECHA Secretariat presented the information on incoming/future applications, expected workload in 2020/2021 and timelines. The secretariat informed also about OPE/NPE AfAs: technical guidance and standard texts for RAC and SEAC rapporteurs. One of the rapporteurs expressed concern on unsynchronised timelines of processing AFA cases in RAC and SEAC. Agreement of the draft opinion in SEAC before discussion in RAC results in pressure to the RAC Rapporteurs to provide preliminary conclusions without RAC scrutiny.	**SECR** to revise dates of the RAC AFA WG in July. **SECR** to correct wording in OPE/NPE AfAs: technical guidance and standard texts for RAC and SEAC rapporteurs.
The stakeholder observer pointed on some unfortunate phrases in the OPE/NPE AfAs: technical guidance and standard texts for RAC and SEAC rapporteurs.	

b) Report from RAC WG on AfAs received during October 2019

The meeting of the 2nd Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation took place on 22-23 October 2019.

Participants: 19 RAC members, five Members' advisers, one regular stakeholder observer and ECHA.

The working group recommended that the following draft opinion were suitable for agreement at the RAC plenary:

- OPE_Sebia (three uses)
- NPE_Sebia (single use)
- OPE_Stago (two uses)
- OPE_BioMarin (two uses)
- OPE_bioMerieux (three uses)
- OPE_Janssen (single use)

The working group recommended that the following draft opinions ware suitable for consideration via the A-listing procedure.

- SC_Ariston (single use)
- SD_Bussi (single use)

ECHA Secretariat presented the Report of the 2nd Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation. RAC took note of the Report.	-

9.2 Authorisation applications

a) Discussion on key issues

1. 17 applications for authorisation from August 2019 submission window (OPE/NPE)

RAC discussed the key issues in the seventeen applications for authorisation.	-

b) Agreement on draft opinions

A. Agreement on draft opinions on AFA by A-listing following the usual scrutiny but without plenary debate

1. **SC_Ariston (1 use)**
2. **SD_Bussi (1 use)**

The Chairman informed the Committee that following the Rapporteurs' proposal, the RAC consultation and the recommendation of the 2nd meeting the RAC AFA WG the draft opinions on the two AFA cases SC Ariston and SD Bussi have been proposed for agreement via the A-listing procedure.

ECHA Secretariat presented the summary of the draft opinions.	**Rapporteur** together with **SECR** to do the final editing of the draft opinions.

RAC agreed by consensus the draft opinions on the two AFA cases SC Ariston and SD Bussi. **SC_Ariston** **Use 1:** *Use of sodium chromate as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances up to 0.70 % by weight (as CrVI) in the refrigerant solution.* RAC concluded that the RMMs and OCs presented in the application are expected to be appropriate and effective in limiting the risk, provided that they are implemented and adhered to. The applicant is using 4.36 tonnes of the substance annually. 8 workers are exposed directly on 1 site in Italy. The highest calculated excess cancer risk for workers for combined exposure for inhalation is 3.54×10^{-5}, (for maintenance and cleaning). The highest RCR for dermal exposure is 0.26 (maintenance and cleaning). The highest excess cancer risk calculated for humans via the environment (local scale for combined routes (inhalation and oral)), is 3.13×10^{-9} (acidic conditions) and 3.14×10^{-9} (alkaline conditions). The estimates of excess cancer risk for workers and for indirect exposure of humans (workers and general population) via environment calculated by the applicant allows a health impact assessment. RAC agreed: • No additional conditions for authorisation • To propose monitoring arrangements for the authorisation - The applicant shall implement and conduct an initial measurement campaign and, at least, annual exposure monitoring programmes for Cr(VI) and annual monitoring of Cr(VI) emissions to wastewater and air. - The information gathered via the measurements and related contextual information shall be used by the applicant to review and confirm the effectiveness of proposed RMM. - The applicant shall ensure that the application of RMMs at his site is in accordance with the hierarchy of control principles.	**SECR** to send the draft opinions to the applicant for commenting.

- The measurements shall be documented, maintained and be made available by the applicant, upon request. - Following implementation of the RMMs and OCs proposed for the new installation, the applicant may reduce the frequency of measurements, once the applicant can clearly demonstrate that exposure to humans and releases to the environment have been reduced to as low a level as technically and practically possible. • recommendations for the review report • The information gathered via the measurements referred to in section 8 points (a) and (b) as well as the outcome and conclusions of the review and any action taken in accordance with point (c) shall be included in any subsequent authorisation review report. **SD_Bussi** **Use 1:** *Use of sodium dichromate as an additive for suppressing parasitic reactions and oxygen evolution, pH buffering and cathode corrosion protection in the electrolytic manufacture of sodium chlorite.* RAC concluded that the RMMs as proposed in the application are expected to be appropriate and effective in limiting the risk, provided that they are implemented and adhered to. The applicant is using 0.1-2 tonnes of the substance annually. 1-50 workers are exposed directly on 1 site in Italy. The highest calculated excess cancer risk for workers combined exposure (for unit operators) is 2.9×10^{-6}. The highest excess cancer risk calculated for humans via the environment (local scale for combined routes (inhalation and oral)), is 8.41×10^{-8}. The estimates of excess cancer risk for workers and for indirect exposure of humans (workers and general population) via the environment allow a health impact assessment. RAC agreed: • No additional conditions for authorisation	

• Proposals for the monitoring arrangements for the authorisation - The applicant shall implement at least annual exposure monitoring programmes for Cr(VI) and emissions to wastewater and air from local exhaust ventilation at least annually. - The information gathered via the measurements shall be used by the applicant to review and confirm the effectiveness of proposed RMM and OCs. - The applicant shall ensure that the application of RMMs at his site is in accordance with the hierarchy of control principles. - The information from the measurements, shall be documented, maintained and be made available by the applicant, upon request. - Following implementation of the RMMs and OCs proposed for the new installation, the applicant may reduce the frequency of measurements, once the applicant can clearly demonstrate that exposure to humans and releases to the environment have been reduced to as low a level as technically and practically possible. • recommendations for the review report - The information gathered via the measurements referred to in section 8 points (a) and (b) as well as the outcome and conclusions of the review and any action taken in accordance with point (c) shall be included in any subsequent authorisation review report.	
B. Agreement on draft opinions on AFA in plenary session	
1. OPE_Sebia	
Use 1: *Industrial use of 4-ter[t]-OPnEO for its "wetting" detergent properties allowing the dissolution, the dilution and the good spreading of substrates and reagents, necessary to optimize the sensitivity of gel electrophoresis in vitro diagnostic tests.* **Use 2:** *Industrial use of 4-tert-OPnEO for its detergent properties in the production of*	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the applicant for commenting.

electrophoresis gels in view of ensuring the positioning of specific proteins necessary for the interpretation of results of gel electrophoresis in vitro diagnostic tests.

Use 3: *Industrial use of 4-tert-OPnEO for its detergent properties resulting in cellular lysis and protein interactions rupture and required for the production of reagents involved in the determination of proteins of interest in gel and capillary electrophoresis IVD test.*

RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to.

Minor concerns regarding the RMMs lead to recommendations for the review report.

The release estimates provided by the applicant are found to be appropriate.

	Used amount kg/year	Release kg/year 4-tert-OPnEO
Use-1	101	0.066-4.4 (Uses 1, 2, and 3 at Lisses plus Use 1 at Paladru)
Use-2	37	0.068-4.7 d (Uses 1, 2, and 3 at Lisses plus Use 2 at Rome)
Use-3	92	0.066-4.4 (Uses 1, 2 and 3 at Lisses)

RAC agreed

- No additional conditions for authorisation
- Recommendations for the review report:
    - RAC recommends the applicant to further assess in any review report the feasibility to collect the remaining liquid wastes from washing the glassware at the site of Lisses (SEBIA) and put it in practice if the outcome of the feasibility study is favourable.

• RAC recommends that the applicant should carry out quarterly/four times per year monitoring of 4-tert-OPnEO (parent substance and its primary degradation products) in the waste water prior to release to the municipal STP at the site of Lisses (SEBIA) and Rome (INTERLAB) =using an analytical method capable of adequately characterising the substance in water and at an appropriately low level of detection. The results should be included in any subsequent review report, including details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. RAC agreed on the draft opinions on uses 1, 2 and 3 by consensus.	
2. NPE_Sebia	
Use 1: *Industrial use of 4-NPnEO for its detergent properties in the production of buffers and reagents in view of ensuring the positioning of specific proteins necessary for the interpretation of gel electrophoresis in vitro diagnostic tests results based on the determination of isoenzymes.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. Annual tonnage used: 2 kg. The use applied for may result in emissions of 0.00016 kg/year (according to monitoring data) or 0.040 kg /year (according to default release values from ERCs) of the substance to the environment. RAC agreed • No additional conditions for authorisation • Recommendations for the review report: ▪ RAC recommends the applicant to further assess in a potential review report the feasibility to collect the remaining liquid wastes from washing the glassware at the site of Lisses	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

(SEBIA) and to put this into practice if the outcome of the feasibility study is favourable. ▪ RAC recommends that the applicant should carry out quarterly/four times per year monitoring of 4-NPnEO (parent substance and its primary degradation products) in the waste water prior to release to the municipal STP at the site of Lisses (SEBIA) using an analytical method capable of adequately characterising the substance in water and at an appropriately low level of detection. The results should be included in any subsequent review report, including details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. RAC agreed on the draft opinion by consensus.	
3. OPE_bioMerieux	
Use 1: *Industrial use of 4-tert-OPnEO for its non-ionic detergent properties in the <u>formulation of reagents</u> for molecular in vitro preparative and testing applications*. RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. Annual tonnage used: 0.976 tonnes/year. The use applied for may result in emissions of 2.87 kg/year (according to monitoring data) or 19.5 kg/year (according to default release values from ERC-2) of the substance to the environment. RAC agreed for: • No additional conditions for authorisation • Recommendations for the review report: ▪ RAC recommends that the applicant should continue quarterly/four times	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the applicant for commenting.

per year monitoring of 4-tert-OPnEO (parent substance and its main degradation products) in the waste water prior to release to the local STP using an analytical method capable of adequately characterising the substance in water and at an appropriately low level of detection. The results should be included in any subsequent review report, including details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. ▪ RAC recommends the applicant to further assess in any review report the feasibility to collect the liquid wastes from washing the glassware and put it in practice if the outcome of the feasibility study is favourable. **Use 2:** *Industrial use of 4-tert-OPnEO for its non-ionic detergent properties in view of controlling the amount of non-specific reactions in the formulation of in vitro reagents for clinical and industrial in-vitro testing immunoassays.* RAC concluded that the operational conditions and risk management measures described in the application are **not** appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk for the environment. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. Annual tonnage used: 0.085 tonnes/year. The use applied for may result in emissions of 90.48 g/year (according to monitoring data) or 1 700 g/year (default release value from ERC-2) of the substance to the environment. RAC agreed for: • Conditions for authorisation ▪ All liquid waste releases which occur during quality control on bulk solutions	

and packaging steps shall be collected and disposed of for adequate treatment within 2 years after the authorisation is granted. • Recommendations for the review report: ▪ RAC recommends that the applicant should continue quarterly/four times per year monitoring of 4-tert-OPnEO (parent substance and its primary degradation products) in the waste water prior to release to the local STP using an analytical method capable of adequately characterising the substance in water and at an appropriately low level of detection. The results should be included in any subsequent review report, including details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. ▪ RAC recommends the applicant to further assess in any review report the feasibility to collect the liquid wastes from washing the glassware and put it in practice if the outcome of the feasibility study is favourable. **Use 3:** *Industrial use of 4-tert-OPnEO for its non-ionic detergent properties, used for the extraction of biological material which is further formulated and coated on articles intended for clinical and industrial in vitro testing applications.* RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk for the environment. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently.	

Annual tonnage used: 0.0013 tonnes/year. The use applied for may result in emissions of 1.3 g/year (according to monitoring data) or 26 g/year (default release value from ERC-6a) of the substance to the environment. RAC agreed for: • Conditions for authorisation ▪ All liquid waste releases which occur during different mixture and antigen preparation steps shall be collected and disposed of for adequate treatment within 2 years after the authorisation is granted. • Recommendations for the review report: ▪ RAC recommends that the applicant should continue quarterly/four times per year monitoring of 4-tert-OPnEO (parent substance and its primary degradation products) in the waste water prior to release to the local STP using an analytical method capable of adequately characterising the substance in water and at an appropriately low level of detection. The results should be included in any subsequent review report, including details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. ▪ RAC recommends the applicant to further assess in any review report the feasibility to collect the liquid wastes from washing the glassware and put it in practice if the outcome of the feasibility study is favourable. RAC agreed on the draft opinions by consensus.	
4. OPE_Stago	
Use 1: *Industrial use of 4-tert-OPnEO for its detergent properties in the process of cell lysing for the production of in-vitro diagnostic*. RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the applicant for commenting.

limiting the risk, provided that they are adhered to. Annual tonnage used: 0.0007 tonnes. According to the applicant the use applied for may result in emissions of 4-tert-OPnEO to the environment in the range of 1-14 g per year. **Use 2:** *Industrial use of 4-tert-OPnEO in view of controlling the amount of non-specific reactions in the production of in-vitro diagnostic reagents.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. Annual tonnage used: 0.0082 tonnes. The use applied for may result in emissions of 4-tert-OPnEO to the environment in the range of 4-164 g per year. RAC agreed for both uses: • No additional conditions for authorisation • Recommendations for the review report: ▪ RAC recommends that the applicant should further assess in a potential review report the feasibility to collect the remaining liquid wastes from rinsing reusable equipment (e.g. glassware, plastic, glass and inox containers) at both sites and put in practice if the outcome of the feasibility study is favourable. ▪ RAC recommends that the applicant should continue at both sites with the quarterly/four times per year monitoring of 4-tert-OPnEO in the waste water prior to release to the local STP using an analytical method capable of adequately characterising the substance and its degradation products in water and at an appropriately low level of detection. The results should be included in any subsequent review report, including details of the sampling point, the analytical method, the concentrations detected and the	

corresponding environmental release values. RAC agreed on the draft opinions on use 1 and 2 by consensus.	
5. OPE_BioMarin	
Use 1: *Industrial use as a surfactant to perform viral inactivation of biological proteins in the manufacture of a biopharmaceutical Final Bulk Drug Substance (FBDS) for an Enzyme Replacement Therapy (BMN250) for the treatment of rare and orphan diseases in the human population.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The recommendations for any review report are expected to allow RAC to evaluate this efficiently. Annual tonnage used: 0.321 tonnes. The use applied for may result in up to approximately 4 g of emissions of 4-tert-OPnEO per year (measured data) of the substance to the environment. **Use 2:** *Industrial use as a surfactant to perform viral inactivation of biological proteins in the manufacture of a biopharmaceutical Final Bulk Drug Substance (FBDS) for Gene Therapy products for the treatment of rare conditions in the human population.* RAC concluded that the operational conditions and risk management measures described in the application are expected to be appropriate and effective in limiting the risk, provided that they are adhered to. The recommendations for any review report are expected to allow RAC to evaluate this efficiently. Annual tonnage used: 0.244 tonnes. The use applied for may result in up to approximately 3.17 g of emissions of 4-tert-OPnEO per year (measured data) of the substance to the environment.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the applicant for commenting.

RAC agreed for both uses: • No additional conditions for authorisation • Recommendations for the review report: ▪ Once full production of Use 1 and 2 is achieved, the applicant shall undertake, a monitoring programme of the waste water prior to release to the local STP to confirm predicted release values. The initial sampling frequency should be sufficient to demonstrate daily fluctuations. ▪ Once established, RAC recommends that thereafter the applicant should, while the plant is in operation, continue with the quarterly /four times per year monitoring of 4-tert-OPnEO and its principal degradation products in in the waste water prior to release to the local STP using an analytical method capable of adequately characterising the substance and its degradation products in water and at an appropriately low level of detection, overcoming the relative high LOQ of the applied method for this application. ▪ The results should be included in any subsequent review report, including details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. RAC agreed on the draft opinions by consensus.	
6. OPE_Janssen	
Use 1: *4-tert-Octylphenol ethoxylate is used as a lysing agent for the permeabilization of the host cell membrane to release adenovirus particles used for the manufacture of vaccines. Its use allows the selective elimination of enveloped adventitious viruses and is compatible with the chemicals needed to control the host cell DNA precipitation in the next process step.* RAC concluded that the operational conditions and risk management measures described in the application are expected to be appropriate and	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

effective in limiting the risk, provided that they are implemented and adhered to. Annual tonnage to be used: 0.27 tonnes/year. The use applied for may result in 0 kg per year emissions of the substance for the environment. RAC agreed for: 1. no additional conditions for the authorisation, 2. no recommendations for the review report. RAC agreed on the draft opinion by consensus.	
10. AOB	
-	
11. Action points and main conclusions of RAC-50	
SECR to upload the adopted action points to CIRCA BC.	

Table 1: CLH opinions which were adopted at RAC-51

1. 24-Epibrassinolide
2. carbendazim (ISO)
3. cypermethrin (ISO)
4. tetrafluoroethylene
5. thiamethoxam (ISO)
6. silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide
7. trinexapac-ethyl (ISO)
8. 1,4-dimethylnaphthalene
9. imazamox (ISO)
10. 3-methylpyrazole

Table 2: CLH opinion which are not finished

1. acetamiprid (ISO)

Table 1

1. 24-Epibrassinolide

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	(3a*S*,5*S*,6*R*,7a*R*,7b*S*,9a*S*,10*R*,12a*S*,12b*S*)-10-[(2*S*,3*R*,4*R*,5*R*)-3,4-dihydroxy-5,6-dimethylheptan-2-yl]-5,6-dihydroxy-7a,9a-dimethylhexadecahydro-3*H*-benzo[*c*]indeno[5,4-*e*]oxepin-3-one; 24-epibrassinolide		78821-43-9	Aquatic Chronic 4	H413		H413			
RAC opinion	TBD	(3a*S*,5*S*,6*R*,7a*R*,7b*S*,9a*S*,10*R*,12a*S*,12b*S*)-10-[(2*S*,3*R*,4*R*,5*R*)-3,4-dihydroxy-5,6-dimethylheptan-2-yl]-5,6-dihydroxy-7a,9a-dimethylhexadecahydro-3*H*-benzo[*c*]indeno[5,4-*e*]oxepin-3-one; 24-epibrassinolide		78821-43-9	Aquatic Chronic 4	H413		H413			
Resulting Annex VI entry if agreed by COM	TBD	(3a*S*,5*S*,6*R*,7a*R*,7b*S*,9a*S*,10*R*,12a*S*,12b*S*)-10-[(2*S*,3*R*,4*R*,5*R*)-3,4-dihydroxy-5,6-dimethylheptan-2-yl]-5,6-dihydroxy-7a,9a-dimethylhexadecahydro-3*H*-benzo[*c*]indeno[5,4-*e*]oxepin-3-one; 24-epibrassinolide		78821-43-9	Aquatic Chronic 4	H413		H413			

2. Carbendazim (ISO)

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	613-048-00-8	carbendazim (ISO); methyl benzimidazol-2-ylcarbamate	234-232-0	10605-21-7	Muta. 1B Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	H340 H360FD H400 H410	GHS08 GHS09 Dgr	H340 H360FD H410			
Dossier submitters proposal	613-048-00-8	carbendazim (ISO); methyl benzimidazol-2-ylcarbamate	234-232-0	10605-21-7	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Skin Sens. 1	**Retain** H400 H410 **Add** H317	**Retain** GHS09 **Add** GHS07	**Retain** H410 **Add** H317		**Add** M=10 M=10	
RAC opinion	613-048-00-8	carbendazim (ISO); methyl benzimidazol-2-ylcarbamate	234-232-0	10605-21-7	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Skin Sens. 1	**Retain** H400 H410 **Add** H317	**Retain** GHS09 **Add** GHS07	**Retain** H410 **Add** H317		**Add** M=10 M=10	
Resulting Annex VI entry if agreed by COM	613-048-00-8	carbendazim (ISO); methyl benzimidazol-2-ylcarbamate	234-232-0	10605-21-7	Muta. 1B Repr. 1B Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H340 H360FD H317 H400 H410	GHS07 GHS08 GHS09 Dgr	H340 H360FD H317 H410		M=10 M=10	

3. Cypermethrin (ISO)

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-421-00-4	cypermethrin *cis/trans* +/- 40/60; (*RS*)-α-cyano-3-phenoxybenzyl (1*RS*,3*RS*;1*RS*,3*SR*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	257-842-9	52315-07-8	Acute Tox. 4* Acute Tox. 4* STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1	H332 H302 H335 H400 H410	GHS07 GHS09 Wng	H332 H302 H335 H410			
Dossier submitters proposal	607-421-00-4	cypermethrin (ISO); α-cyano-3-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate; cypermethrin cis/trans +/- 40/60	257-842-9	52315-07-8	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** STOT RE 2 **Modify** Acute Tox. 4 Acute Tox. 4	**Retain** H332 H302 H400 H410 **Add** H373 (nervous system)	**Retain** GHS07 GHS09 Wng **Add** GHS08	**Retain** H332 H302 H410 **Add** H373 (nervous system)		**Add** M=100 M=1000	
RAC opinion	607-421-00-4	cypermethrin (ISO); α-cyano-3-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate; cypermethrin cis/trans +/- 40/60	257-842-9	52315-07-8	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** STOT RE 2 **Modify** Acute Tox. 4 Acute Tox. 4	**Retain** H332 H302 H400 H410 **Add** H373 (nervous system)	**Retain** GHS07 GHS09 Wng **Add** GHS08	**Retain** H332 H302 H410 **Add** H373 (nervous system)		**Add** oral; ATE = 500 mg/kg bw inhal; ATE = 3.3 mg/L (dusts & mists) M=100000 M=100000	
Resulting Annex VI entry if agreed by COM	607-421-00-4	cypermethrin (ISO); α-cyano-3-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate; cypermethrin cis/trans +/- 40/60	257-842-9	52315-07-8	Acute Tox. 4 Acute Tox. 4 STOT SE 3 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H332 H302 H335 H373 (nervous system) H400 H410	GHS07 GHS08 GHS09 Wng	H332 H302 H335 H373 (nervous system) H410		oral; ATE = 500 mg/kg bw inhal; ATE = 3.3 mg/L (dusts & mists) M=100000 M=100000	

4. Tetrafluoroethylene

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	tetrafluoroethylene	204-126-9	116-14-3	Carc. 1B	H350	GHS08	H350			
RAC opinion	TBD	tetrafluoroethylene	204-126-9	116-14-3	Carc. 1B	H350	GHS08 Dgr	H350			
Resulting Annex VI entry if agreed by COM	TBD	tetrafluoroethylene	204-126-9	116-14-3	Carc. 1B	H350	GHS08 Dgr	H350			

5. Thiamethoxam (ISO)

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	613-267-00-9	thiamethoxam (ISO); 3-(2-chloro-thiazol-5-ylmethyl)-5-methyl[1,3,5]oxadiazinan-4-ylidene-*N*-nitroamine	428-650-4	153719-23-4	Acute Tox. 4* Aquatic Acute 1 Aquatic Chronic 1	H302 H400 H410	GHS07 GHS09 Wng	H302 H410		M=10	
Dossier submitters proposal	613-267-00-9	thiamethoxam (ISO); 3-(2-chloro-thiazol-5-ylmethyl)-5-methyl[1,3,5]oxadiazinan-4-ylidene-*N*-nitroamine	428-650-4	153719-23-4	**Retain** Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1 **Add** Flam. Sol. 1 Repr. 2	**Retain** H302 H400 H410 **Add** H228 H361	**Retain** GHS07 GHS09 **Add** GHS02 GHS08 **Modify** Dgr	**Retain** H302 H410 **Add** H228 H361		**Add** oral: ATE = 800 mg/kg bw **Retain** M=10 **Add** M=10	
RAC opinion	613-267-00-9	thiamethoxam (ISO); 3-(2-chloro-thiazol-5-ylmethyl)-5-methyl[1,3,5]oxadiazinan-4-ylidene-*N*-nitroamine	428-650-4	153719-23-4	**Retain** Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1 **Add** Repr. 2	**Retain** H302 H400 H410 **Add** H361fd	**Retain** GHS07 GHS09 Wng **Add** GHS08	**Retain** H302 H410 **Add** H361fd		**Add** oral: ATE = 780 mg/kg bw **Retain** M=10 **Add** M=10	
Resulting Annex VI entry if agreed by COM	613-267-00-9	thiamethoxam (ISO); 3-(2-chloro-thiazol-5-ylmethyl)-5-methyl[1,3,5]oxadiazinan-4-ylidene-*N*-nitroamine	428-650-4	153719-23-4	Repr. 2 Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H361fd H302 H400 H410	GHS07 GHS08 GHS09 Wng	H361fd H302 H410		oral: ATE = 780 mg/kg bw M=10 M=10	

6. Silanamine

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No Current Annex VI Entry										
Dossier submitters proposal	TBD	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface-treated silicon dioxide	272-697-1	68909-20-6	STOT RE 2	H373 (lungs, inhalation)	GHS08 Wng	H373 (lungs, inhalation)	EUH 066		
RAC opinion	TBD	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface-treated silicon dioxide	272-697-1	68909-20-6	Acute Tox. 2 STOT RE 2	H330 H373 (lung, inhalation)	GHS06 GHS08 Dgr	H330 H373 (lung, inhalation)	EUH 066	Inhalation: ATE = 0.45 mg/L (dusts & mists)	
Resulting Annex VI entry if agreed by COM	TBD	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface-treated silicon dioxide	272-697-1	68909-20-6	Acute Tox. 2 STOT RE 2	H330 H373 (lung, inhalation)	GHS06 GHS08 Dgr	H330 H373 (lung, inhalation)	EUH 066	Inhalation: ATE = 0.45 mg/L (dusts & mists)	

7. Trinexapac-ethyl (ISO)

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	trinexapac-ethyl (ISO); ethyl 4-[cyclopropyl(hydroxy)methylene]-3,5-dioxocyclohexanecarboxylate	-	95266-40-3	Skin Sens. 1B Aquatic Chronic 1	H317 H410	GHS07 GHS09 Wng	H317 H410		M=1	
RAC opinion	TBD	trinexapac-ethyl (ISO); ethyl 4-[cyclopropyl(hydroxy)methylene]-3,5-dioxocyclohexanecarboxylate	-	95266-40-3	STOT RE 2 Skin Sens. 1B Aquatic Chronic 1	H373 (GI tract) H317 H410	GHS08 GHS07 GHS09 Wng	H373 (GI tract) H317 H410		M=1	
Resulting Annex VI entry if agreed by COM	TBD	trinexapac-ethyl (ISO); ethyl 4-[cyclopropyl(hydroxy)methylene]-3,5-dioxocyclohexanecarboxylate	-	95266-40-3	STOT RE 2 Skin Sens. 1B Aquatic Chronic 1	H373 (GI tract) H317 H410	GHS08 GHS07 GHS09 Wng	H373 (GI tract) H317 H410		M=1	

8. 1,4-dimethylnaphthalene

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal		1,4-dimethylnaphthalene	209-335-9	571-58-4	Asp. Tox. 1 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 2	H304 H319 H400 H411	Dgr GHS07 GHS08 GHS09	H304 H319 H410		M=1	
RAC opinion		1,4-dimethylnaphthalene	209-335-9	571-58-4	Asp. Tox. 1 Acute Tox. 4 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 3	H304 H302 H319 H400 H412	Dgr GHS07 GHS08 GHS09	H304 H302 H319 H410		oral: ATE = 1300 mg/kg bw M=1 A	
Resulting Annex VI entry if agreed by COM		1,4-dimethylnaphthalene	209-335-9	571-58-4	Asp. Tox. 1 Acute Tox. 4 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 3	H304 H302 H319 H400 H412	Dgr GHS07 GHS08 GHS09	H304 H302 H319 H410		oral: ATE = 1300 mg/kg bw M=1 A	

9. Imazamox (ISO)

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATEs	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	613-208-00-7	imazamox (ISO); (*RS*)-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-5-methoxymethylnicotinic acid	-	114311-32-9	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410			
Dossier submitters proposal	613-208-00-7	imazamox (ISO); (*RS*)-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-5-methoxymethylnicotinic acid	-	114311-32-9	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Repr. 2	**Retain** H400 H410 **Add** H361d	**Retain** GHS09 Wng **Add** GHS08	**Retain** H410 **Add** H361d		**Add** M=10 M=10	
RAC opinion	613-208-00-7	imazamox (ISO); (*RS*)-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-5-methoxymethylnicotinic acid	-	114311-32-9	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Repr. 2	**Retain** H400 H410 **Add** H361d	**Retain** GHS09 Wng **Add** GHS08	**Retain** H410 **Add** H361d		**Add** M=10 M=10	
Resulting entry in Annex VI if agreed by COM	613-208-00-7	imazamox (ISO); (*RS*)-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-5-methoxymethylnicotinic acid	-	114311-32-9	Repr. 2 Aquatic Acute 1 Aquatic Chronic 1	H361d H400 H410	GHS08 GHS09 Wng	H361d H410		M=10 M=10	

10. 3-methylpyrazole

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	3-methylpyrazole	215-925-7	1453-58-3	Repr. 1B Acute Tox. 4 STOT RE 1 Skin Corr. 1 Eye Dam. 1	H360D H302 H372 (lung) H314 H318	GHS08 GHS07 GHS05 Dgr	H360D H302 H373 (lung) H314		oral: ATE = 500 mg/kg bw	
RAC opinion	TBD	3-methylpyrazole	215-925-7	1453-58-3	Repr. 1B Acute Tox. 4 STOT RE 2 Skin Corr. 1 Eye Dam. 1	H360D H302 H373 (lung) H314 H318	GHS08 GHS07 GHS05 Dgr	H360D H302 H373 (lung) H314		oral: ATE = 500 mg/kg bw	
Resulting Annex VI entry if agreed by COM	TBD	3-methylpyrazole	215-925-7	1453-58-3	Repr. 1B Acute Tox. 4 STOT RE 2 Skin Corr. 1 Eye Dam. 1	H360D H302 H373 (lung) H314 H318	GHS08 GHS07 GHS05 Dgr	H360D H302 H373 (lung) H314		oral: ATE = 500 mg/kg bw	

Table 2

1. Acetamiprid (ISO)

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	608-032-00-2	acetamiprid (ISO); (*E*)-N^1-[(6-chloro-3-pyri-dyl)methyl]-N^2-cyano-N^1-methylacetamidine		135410-20-7	Acute Tox. 4* Aquatic Chronic 3	H302 H412	GHS07 Wng	H302 H412			
Dossier submitters proposal	608-032-00-2	acetamiprid (ISO); (1*E*)-*N*-[(6-chloropyridin-3-yl)methyl]-*N*'-cyano-*N*-methylethanimidamide; (*E*)-*N*^{1}-[(6-chloro-3-pyridyl)methyl]-*N*^{2}-cyano-*N*^{1}-methylacetamidine		135410-20-7; 160430-64-8	**Add** Carc. 2 Repr. 2 Aquatic Acute 1 **Modify** Acute Tox. 3 Aquatic Chronic 1	**Add** H351 H361d H400 **Modify** H301 H410	**Add** GHS06 GHS08 GHS09 **Modify** Dgr **Remove** GHS07	**Add** H351 H361d **Modify** H301 H410		**Add** M=10 M=100	
RAC opinion	608-032-00-2	acetamiprid (ISO); (1*E*)-*N*-[(6-chloropyridin-3-yl)methyl]-*N*'-cyano-*N*-methylethanimidamide; (*E*)-*N*^{1}-[(6-chloro-3-pyridyl)methyl]-*N*^{2}-cyano-*N*^{1}-methylacetamidine		135410-20-7; 160430-64-8	**Add** Aquatic Acute 1 **Modify** Aquatic Chronic 1	**Add** H400 **Modify** H410	**Add** GHS09	**Modify** H410		**Add** M=10 M=10	
Resulting Annex VI entry if agreed by COM	608-032-00-2	acetamiprid (ISO); (1*E*)-*N*-[(6-chloropyridin-3-yl)methyl]-*N*'-cyano-*N*-methylethanimidamide; (*E*)-*N*^{1}-[(6-chloro-3-pyridyl)methyl]-*N*^{2}-cyano-*N*^{1}-methylacetamidine		135410-20-7; 160430-64-8	TBD after HH agreed						

Part I. List of Attendees of the RAC-51 meeting

RAC Members
Aquilina Gabriele
Andreou Kostas
Barański Bogusław
Biró Anna
Bjørge Christine
Borg Daniel
Brovkina Julija
Carvalho João
Chankova-Petrova Stephka
Chiurtu Elena (co-opted member)
Czerczak Sławomir
de la Flor Tejero Ignacio
Dobrev Ivan
Dunauskienė Lina
Geoffroy Laure
Gruiz Katalin
Hakkert Betty
Hartwig Andrea (co-opted member)
Heederik Dick (co-opted member)
Husa Stine
Kadiķis Normunds
Kapelari Sonja
Karadjova Irina
Leinonen Riitta
Losert Annemarie
Lund Bert-Ove
Martínek Michal
Menard Srpčič Anja
Moeller Ruth
Moldov Raili
Murray Brendan
Neumann Michael
Paris Pietro
Pribu Mihaela
Printemps Nathalie
Pronk Marja
Rucki Marian
Santonen Tiina
Schlüter Urs
Schulte Agnes
Séba Julie
Sørensen Hammer Peter
Sogorb Miguel A.
Spetseris Nikolaos
Stahlmann Ralf
Tobiassen Lea Stine
Tsitsimpikou Christina
Užomeckas Žilvinas
Van der Haar Rudolf (co-opted member)
Varnai Veda
Apologies, Members
Agapiou Agapios
Branisteanu Radu (co-opted member)
Dungey Stephen
Mullooly Yvonne
Smith Andrew
Zeljezic Davor

Members' advisers
Granato Giuseppe (Pietro Paris)
Hoffmann Frauke (Agnes Schulte)_formaldehyde
Hyytinen Eija-Riitta (Riitta Leinonen)
Kuittinen Marko (Riitta Leinonen)
Peczkowska Beata (Boguslaw Baranski)
Sebbio Claudia (Paris Pietro)
Sonnenburg Anna (Ralf Stahlmann)_3-methylpyrazole
Commission
Sylvain Bintein (DG ENV)
Miriam Gutierrez-Medina (DG GROW)
Zinta Podniece (DG EMPL)
Invited experts
Rodriguez Wendy (replacing RAC member Julie Seba)
Susana Viegas (replacing RAC Member Joao Carvalho)
Dossier submitters
Mörk Anna-Karin (SE)_skin sensitisers in textile
Steward Alexandra (SE)_skin sensitisers in textile

Regular stakeholder observers
Barry Frank (ETUC)
Bernard Alice (ClientEarth)
Van de Broeck Steven (Cefic)
Janosi Amaya (Cefic)
Comini Andrea (EuCheMS)
Romano Mozo Dolores (EEB)
Rowe Rocky (ECPA)
Verougstraete Violaine (Eurometaux)
Occasional stakeholders
Angiulli Francesca (A.I.S.E)_Restriction: microplastics
Buijs Nathalie (MedTech Europe)_OEL: lead and diisocyanates; Restriction: cobalt salts, microplastics, siloxanes; AfA: all AfAs
Drmac Dunja (Euratex)_Restriction: skin sensitisers in textile
Stevens Gil (EDANA)_Restriction: skin sensitisers in textile, microplastics
Tillieux Geoffroy (EuPC)_OEL: lead and diisocyanates
Stakeholder experts
Binks Steve (Eurometaux/European Association of the metals Industry)_OEL: lead
Bonifay Sebastien (ECPA/ECPA microplastics users)_Restriction: microplastics
Busch Michaela (ECPA/Nisso)_CLH: acetamiprid)
Goettel Manuela (ECPA/BASF)_CLH: imazamox
Green Dannielle (EEB/School of Life Sciences, Anglia Ruskin University)_Restriction: microplastics
Jackson Ffion (MedTech/Siemens Healthineers)_Restriction: microplastics
Jacobi Sylvia (Cefic/Sector group Catalysts Europe)_Restriction: cobalt salts

Jenner Karen (AISE/Givaudan)_Restriction: microplastics	**REMOTE PARTICIPANTS**
Klasse Hans-Juergen (Cefic/AlzChem Trostberg GmbH)_CLH: calcium cyanamide	
Krueger Ines (EuPC/Covestro Deutschland AG)_OEL: diisocyanates	**RAC Members**
Leibold Edgar (Cefic/Formacare)_Restriction: formaldehyde	Carvalho Joao
Lloyd Sara (ECPA/Syngenta)_CLH: thiamethoxam, trinexapac-ethyl	Losert Annemarie
Mortier Nike (ClientEarth/OWS)_Restriciton: microplastics	Mullooly Yvonne
Ott Wolfgang (EDANA/Kelheim fibres)_Restrcition: skin sensitisers in textile, microplastics	Printemps Nathalie
Pfois Pierfrancesco (Euratex/ETAD)_Restriction : skin sensitisers in textile	Schlueter Urs
Plotzke Kathy (Cefic/CES-Silicone Europe)_Restriction : siloxanes	Tobiassen Lea Stine
Serrano Ramon Blanca (Cefic/Cefic)_Restriction: microplastics	
Shenton Martyn James (Cefic/AGC Chemicals Europe Ltd)_CLH: tetrafluoroethylene	**Members' advisers**
Stein Juergen (ECPA/Arysta/UPL)_CLH: cypermethrin	Boel Els (Julie Seba)
Terlingen Leon (Eurometaux/Fertilizers Europe)_Restiction: microplastics	Catone Tiziana (Gabriele Aquilina)
Unterberger Elif (Cefic/BASF)_OEL: diisocyanates	Esposito Dania (Pietro Paris)
Viegas Vanessa (Eurometaux/Cobalt Institute and Cobalt REACH Consortium Ltd)_Cobalt salts	Kinzl Max (Annemarie Losert)
--------	Marinkovic Marino (Betty Hakkert)
	Vega Milagros (Joao Carvalho)
	Woutersen Marjolijn (Betty Hakkert)

SEAC rapporteurs
Bergs Ivars (cobalt salts)
Fankhauser Simone (cobalt salts)
Thiele Karen (microplastics)
Dossier submitters
BE
Lefebvre Frederic (cypermethrin)
FR
Dubois Celine (skin sensitisers)
Fiore Karine (skin sensitisers)
IE
Conway Louise (tetrafluoroethylene)
LT
Paltanaviciene Audra (trinexapac-ethyl)
NL
Van Herwijnen Rene (acetamiprid and 1,4-dimethylnaphthalene)
Groothuis Floris (acetamiprid and 1,4-dimethylnaphthalene)
NO
Correll Myhre Ingunn (PFHxS)
Fotland Tor Øystein (PFHxS)
SE
Carlsson Feng Mattias (skin sensitisers)
Johansson Olof (microplastics)
Commission
Baricic Peter
Bertato Valentina
Blass Rico Ana Maria
Hualde-Grasa Eva Patricia
Jezso Veronika

Kusendila Christophe
Lekatos Stylianos
Rozwadowski Jacek
Tosetti Patrizia
ECHA staff in plenary
Ajao Charmaine
Berges Markus
Blainey Mark
Bowmer Tim, Chairman
Broeckaert Fabrice
Di Bastiano Augusto
Dvorakova Dana
Figuiere Romain
Gmeinder Michael
Hellsten Kati
Henrichson Sanna
Jones Stella
Karjalainen Antti
Kivelä Kalle
Kokkola Leila
Lapenna Silvia
Lefevre-Brevart Sandrine
Logtmeijer Christiaan
Ludborzs Arnis
Marques-Camacho Mercedes
Mazzega Sbovata Silvia
Montiel Pablo
Mushtaq Fesil
Myöhänen Kirsi
Nicot Thierry

Nogueiro Eugénia	
Nygren Jonas	
Orispää Katja	
O´Rourke Regina	
Ottati Maria	
Peltola Jukka	
Peltola-Thies Johanna	
Pennese Daniele	
Perazzolo Chiara	
Prevedouros Konstantinos	
Regil Pablo	
Reuter Ulrike	
Roggeman Maarten	
Sadam Diana	
Simoes Ricardo	
Simpson Peter	
Smilovici Simona	
Sosnowski Piotr	
Stockmann-Juvala Helene	
Tanarro Celia	
Uphill Simon	
Uphoff Andreas	
Vaananen Virpi	
Vainio Matti	
Van Haelst Anniek	

Part II. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-51 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-51 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-51 meeting

ANNEX IV Administrative issues and information items

25 November 2019
RAC/A/51/2019

Annex I (RAC-51)

Final Agenda
51st meeting of the Committee for Risk Assessment

25-28 November 2019
and
3 December – 5 December 2019

ECHA Conference Centre (Annankatu 18, Helsinki)

Monday 25 November starts at 14.00
Thursday 28 November breaks at 13.00
Tuesday 3 December resumes at 09.00
Thursday 5 December ends at 13.00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/51/2019
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Appointment of (co-)rapporteurs

a) Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits

For agreement

Item 5 – Report from other ECHA bodies and activities

a) Report on RAC 50 action points, written procedures and update on other ECHA bodies

RAC/51/2019/01
Room document
For information

b) RAC workplan for all processes

For information

c) Revised rules of procedure

RAC/51/2019/02
For agreement

Item 6 –Health based exposure limits at the workplace

a) Discussion on key issues
   1) Lead and its compounds
   2) Diisocyanates

For discussion

Item 7 – Harmonised classification and labelling (CLH)

7.1 General CLH issues

a) Corrigendum to the adopted opinion on L-(+)- lactic acid
b) Physical hazards

For information/discussion

7.2 CLH dossiers

A. Hazard classes for agreement without plenary debate (fast-track)

- 24-epibrassinolide: physical hazards (explosives, flammable solids, pyrophoric solids, self-heating substances, oxidising solids), human health hazards
- carbendazim (ISO): physical hazards (explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids), skin sensitisation, hazards to the aquatic environment
- silanamine: physical hazards (explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance or mixture which in contact with water emits flammable gas, oxidising solid, substance or mixture corrosive to metals), acute toxicity (dermal and inhalation routes of exposure), skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, hazards to the aquatic environment
- trinexapac-ethyl (ISO): physical hazards (explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance or mixture which in contact with water emits flammable gas, oxidising liquid, oxidising solid), acute toxicity, STOT SE, skin corrosion/irritation, serious eye damage/irritation, germ cell mutagenicity, carcinogenicity

- 1,4-dimethylnaphthalene: physical hazards (explosive, flammable gas, flammable liquid, self-reactive substance or mixture, pyrophoric liquid, substance or mixture which in contact with water emits flammable gas, oxidising liquid), acute toxicity (dermal and inhalation routes of exposure), skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, STOT SE, STOT RE, hazards to the aquatic environment
- imazamox (ISO): hazards to the aquatic environment
- 3-methylpyrazole: acute oral toxicity, skin corrosion / irritation, serious eye damage / eye irritation

B. Hazard classes for agreement with plenary debate

1) 24-epibrassinolide
2) acetamiprid (ISO)
3) cypermethrin (ISO)
4) tetrafluoroethylene
5) thiamethoxam (ISO)
6) silanamine
7) trinexapac-ethyl (ISO) (human health hazards only)
8) 1,4-dimethylnaphthalene
9) imazamox (ISO)
10) 3-methylpyrazole

For discussion and adoption

Item 8 – Restrictions

8.1 General restriction issues

a) Report from the Restrictions Efficiency Task Force

For information

8.2 Restriction Annex XV dossiers

a) Opinion development
   1) Calcium cyanamide in fertilisers – first draft opinion
   2) Skin sensitisers in textile – second draft opinion
   3) Perfluorohexane-1-sulphhonic acid, its salts and related substances – Update from public consultation comments
   4) Microplastics – fourth draft opinion
   5) Formaldehyde and formaldehyde releasers – third draft opinion

For discussion

   6) Cobalt salts – final draft opinion
   7) Siloxanes (D4, D5, and D6) – final draft opinion

For discussion and adoption

Item 9 – Authorisation

9.1 General authorisation issues

a) Update on incoming/future applications
b) Report from RAC WG on AfAs received during October 2019

For information/discussion

9.2 Authorisation applications

a) Discussion on key issues
   1) 17 applications for authorisation from August 2019 submission window (OPE/NPE)

For discussion

b) Agreement on draft opinions

A. Hazard classes for agreement without plenary debate (fast-track)

1) SC_Ariston (1 use)
2) SD_Bussi (1 use)

B. Hazard classes for agreement with plenary debate

1) OPE_Sebia (3 uses)
2) NPE_Sebia (1 use)
3) OPE_bioMerieux (3 uses)
4) OPE_Stago (2 uses)
5) OPE_BioMarin (2 uses)
6) OPE_Janssen (1 use)

For discussion and agreement

Item 10 – AOB

Item 11 – Action points and main conclusions of RAC-51

Table with Conclusions and Action points from RAC-51

For adoption

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-51 – WEEK 1

Please note that this timeline is provisional. Changes can be made before and during the meeting in order to accommodate the discussions.

Monday 25 November: Afternoon session

Item 1 – Welcome and Apologies
Item 2 – Adoption of the Agenda
Item 3 – Declarations of conflicts of interest to the Agenda
Item 5 - RAC Work Plan for Restriction, Authorisation and C&L processes
Item 5 - Revised Rules of Procedure
Item 6 - Occupational exposure limits
Item 8 - Restrictions

Tuesday 26 November: Morning session

Item 8 - Restrictions

Tuesday 26 November: Afternoon session

Item 8 - Restrictions

Wednesday 27 November: Morning session

Item 8 - Restrictions

Wednesday 27 November: Afternoon session

Item 8 - Restrictions
Item 9 - Authorisation applications

Thursday 28 November: Morning session

Item 9 - Authorisation applications

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-51 – WEEK 2

Please note that this timeline is provisional. Changes can be made before and during the meeting in order to accommodate the discussions.

Tuesday 3 December: Morning session

Item 1 – Welcome and Apologies

Item 3 – Declarations of conflicts of interest to the Agenda

Item 7 - CLH dossiers

Tuesday 3 December: Afternoon session

Item 7 - CLH dossiers

Wednesday 4 December: Morning session

Item 7 - CLH dossiers

Wednesday 4 December: Afternoon session

Item 7 - CLH dossiers

Thursday 5 December: Morning session

Item 4 - Appointment of rapporteurs

Item 7 - CLH dossiers

Item 10 - AOB

Annex II (RAC 51)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC 51 meeting.

Document number	Title
RAC/A/51/2019	Final Draft Agenda
RAC/51/2019/01 Room document	Administrative issues and information items
RAC/51/2019/02	Revised rules of procedure
RAC/51/2019/03 Room document	Amendment to the RAC opinion on L-(+)-lactic acid in relation to the generic concentration limits (GCL) for skin corrosion/irritation and serious eye damage/eye irritation
RAC/51/2019/04 Room document	CLH/Physical hazard note

Annex III (RAC-51)

The following participants, including those for whom the Chairman declared the interest on their behalf, declared potential conflicts of interest with the Agenda items (according to Art 9 (2) of RAC RoPs)

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
ALREADY DECLARED AT PREVIOUS RAC PLENARY MEETING(S)		
Applications for Authorisation		
All chromates	Urs SCHLUTER	Institutional & personal involvement; asked to refrain from voting in the event of a vote on this group of substances - other mitigation measures may be applied by the Chairman.
Harmonised classification & labelling		
Trinexapac-ethyl (ISO) **LT**	Lina DUNAUSKIENE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Zilvinas UZOMECKAS	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
Restrictions		
Calcium cyanamide	Ruth MOELLER	Worked as consultant on human health risk assessment of cyanamide – personal involvement
Perfluorohexane-1-sulphhonic acid, its salts and related substances	Christine BJORGE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Stine HUSA	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Skin sensitisers in textile	Daniel BORG	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Partial personal involvement.
	Nathalie PRINTEMPS	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Harmonised classification & labelling		
carbendazim (ISO) **DE**	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

Dossier / DS	RAC Member	Reason for potential CoI / Working for
	Urs SCHLUTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
1) acetamiprid (ISO) **2) 1,4-dimethylnaphthalene** **NL**	Betty HAKKERT	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Marja PRONK	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
1) thiamethoxam (ISO) **2) imazamox (ISO)** **3) silanamine** **FR**	Nathalie PRINTEMPS	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Tiina Santonen	Personal involvement in amorphous silicon dioxide compounds during her previous work (before joining RAC).
1) 3-methylpyrazole **2) cypermethrin (ISO)** **BE**	Julie SEBA + Wendy Rodriguez (adviser)	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
1) 24-epibrassinolide **AT**	Annemarie LOSERT	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

Annex IV (RAC-51)

ADMINISTRATIVE ISSUES AND INFORMATION ITEMS

1 Status report on the RAC-50 Action Points

The RAC-50 action points due for RAC-51 are completed.

2 Outcome of written procedures & other consultations

2.1 Written procedures for adoption of RAC opinions / minutes of the meeting

Opinions / minutes adopted via written procedure	Deadline	Report on the outcome
Written procedure for adoption of the minutes of RAC-50	13 November 2019	closed

2.2 RAC consultations (status by 19 November 2019)

Subject / document	Deadline	Status / follow-up
Harmonised classification and labelling		
24-Epibrassinolide	5 November 2019	closed
acetamiprid (ISO) – *ENV only*	5 November 2019	closed
carbendazim (ISO)	28 October 2019	closed
cypermethrin (ISO)	5 November 2019	closed
tetrafluoroethylene	5 November 2019	closed
thiamethoxam (ISO)	5 November 2019	closed
silanamine	5 November 2019	closed
trinexapac-ethyl (ISO)	14 November 2019	closed
1,4-dimethylnaphthalene	5 November 2019	closed
imazamox (ISO)	31 October 2019	closed
3-methylpyrazole	5 November 2019	closed
Application for Authorisation / Review Report		
146_CT_TataSteel 147_CTPht_AO_Bilbaina 148_CTPht_DEZA 149_CTPht_Nalon 150_CTPht_AO_Koppers 151_CTPht_AO_Rutgers 152_CTPht_AO_RainCarbon 153_CTPht_Bilbaina 155_OPE_Siemens_2 157_OPE_Kedrion 158_OPE_Sanofi 159_OPE_Merck 161_OPE_Swords 166_OPE_Ompi	2 October 2019	closed

Subject / document	Deadline	Status / follow-up
167_OPE_Roche 168_OPE_Vetter 169_OPE_Nordisk 171_OPE_Wallac 173_OPE_Sobi 174_OPE_Eli_Lilly 175_OPE_Rousselot 176_OPE_Abbott_1 177_OPE_Abbott_2 178_OPE_Janssen 179_OPE_Octapharma 181_OPE_NPE_Roche 183_NPE_GEHC_Bio-Sciences Consultations on applications for authorisation		
154_OPE_Siemens_1, 156_OPE_Hospira, 160_OPE_Merck_2, 162_OPE_LFB, 163_OPE_Rentschler, 164_OPE_Baxter, 165_OPE_bioMerieux_2, 170_OPE_Diasorin, 172_OPE_DIAGAST, 180_OPE_NPE_Bio-Rad, 182_NPE_Abbott, 184_OPE_Lilly, 185_OPE_NPE_Idexx, 186_OPE_NPE_Beckman, 187_OPE_AGC, 188_OPE_Wallac_2, 189_OPE_Lonza, 190_OPE_TEVA, 191_NPE_Sekisui Consultations on applications for authorisation	8 January 2020	ongoing
Restrictions		
Consultations on the third draft opinion on formaldehyde and formaldehyde releasers, and on the fourth draft opinion on Microplastics	12 December 13 December 2019	ongoing
Consultations on the second versions of the draft opinions on PFHxS and on skin sensitisers, on the third version of the draft opinion on D4/D5/D6, and on the sixth version of the draft opinion on Cobalt salts	22 November 2019 20 November 2019 18 November 2019 20 November 2019	closed
Art. 77. 3. c request		
no consultations		
Health based exposure limits at the workplace		
Consultations on the two scientific reports for evaluation of limit values for diisocyanates and 'lead and its compounds.	28 October – 2 December	ongoing

2.3 Calls for expression of interest

Calls for expression of interest		Date	Outcome
Harmonised classification and labelling			
Call for expression of interest in CLH dossiers	11 – 18 November 2019	one volunteer	
Application for Authorisation			
Call for expression of interest in rapporteurship on applications for authorisation on SVHCs in 12 ltest entries in Annex XIV of the REACH Regulation. Full list of the latest entries is published in Annex of the Commission Regulation (EU) 2017/999[1].			
Restriction Call for expression of interest for (co-)rapporteurs on restriction proposal PFHxA	15 October – 31 October 2019	No volunteers	

2.4 Written procedures for the appointment of (co-)rapporteurs

Appointment of (Co-)rapporteur(s)	Substance	Deadline	Outcome
Harmonised classification and labelling			
Written procedure for the appointment of (co-)rapporteurs	**bisphenol A; 4,4'-isopropylidenediphenol** (EC 201-245-8, CAS 80-05-7)	31 October 2019	closed No comments were received from RAC members on the recommendation of the Chairman; the RAC (co-)Rapporteurs were appointed with tacit agreement.
Restrictions – no written procedures			
Applications for Authorisation– no written procedures			

2.5 Follow-up on the opinions on applications for authorisation adopted by RAC and SEAC44

Opinion(s)	Sent on
Opinions sent to the European Commission, the Member States and applicants	
CT_Thyssen (2 opinions)	5 September 2019
CT_Aloys (1 opinion) CT_Keuco (2 opinions) CT_Schell (1 opinion) CT_Ideal (2 opinions)	19 September 2019
OPE_Ortho (2 opinions)	23 October 2019

[1] Commission Regulation (EU) 2017/999 of 13 June 2017 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)