RAC/M/50/2019

Final

15 November 2019

Minutes of the 50th Meeting of the Committee for Risk Assessment (RAC 50)

Monday 9, 14.00 to Friday 13 September, 13.00 and Monday 16, 14.00 to Friday 20 September, 13.00

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 50th meeting of the Committee for Risk Assessment (RAC 50). Apologies were received from four Members.

The Chairman noted that the RAC-49 minutes are adopted and they have been uploaded to S-CIRCABC and published on the ECHA website.

The Chairman was pleased to report that this was the 50th meeting of the Committee for Risk Assessment and a milestone in what has already become a long history of achievement, with more than 500 adopted opinions.

He noted that UK Officials had been withdrawn from participating in meetings of EU bodies up to the end of October and that this applied to all ECHA Committees and the Forum, including RAC.

He informed that improving the authorisation process is a top priority for ECHA and that at the beginning of September 2019, the Agency had published the revised formats used by RAC and SEAC for their application for authorisation (AfA) opinions. These new formats support opinions with all relevant technical and scientific elements for decision-making by the European Commission, while leaving policy judgements to the latter body. They help to standardise the opinion texts to allow rapporteurs to form consistent and concise opinions. ECHA has also informed Industry and applicants that they should consider whether they would need to submit a substitution plan as part of their applications. This is the case if there are suitable alternatives available in general but they are not yet feasible for the applicant. He concluded that the new template is for immediate implementation.

The Chairman then informed that as an efficiency measure, the draft 'outline agenda' provided to Members would be discontinued in its current form. With the quarterly work-plan and the provisional timeline for each meeting, the available information should be sufficient for everyone to plan their meetings. Finally, he also noted that later in the year, the secretariat will inform the Members regarding changes to the manner of preparing the minutes for the plenary meetings and on the structure of opinions.

The participants were informed that the meeting would not be recorded. A full list of participants would be given in Part III of the minutes.

2. Adoption of the Agenda

The Chairman reviewed the agenda for the meeting (RAC/A/50/2019). The Committee adopted its agenda and agreed to include the following item proposed by the Secretariat under Any Other Business, Agenda Item 9:

- "Qualification of risks to the environment from 4-tert-OP".

He noted that the chromate applications submitted by Bussi and Ariston had been removed from the agenda and will go forward for consideration by the RAC AfA Working group in October and agreement at RAC 51 in Nov/Dec.

The agenda and the list of meeting documents, including conclusions and action points are attached to these minutes as Annexes I and II, respectively.

3. Declarations of conflicts of interests to the Agenda

The Chairman declared that he had no potential conflict of interest to any agenda points for the meeting.

The Chairman further requested all participants to declare any potential conflicts of interest to any of the agenda items. In all, 16 Members declared potential conflicts of interest, each to specific agenda items, the majority related to concurrent employment of Members at agencies submitting dossiers to RAC but who had not been involved in the preparation. In the event of a vote, these Members were requested to refrain from voting on the respective agenda items, as stated in Article 9.2 of the RAC Rules of Procedure. Where Members declared that they had contributed to the preparation of a substance dossier for consideration by RAC, or similar potential conflict, they were asked to refrain from voting and the Chairman noted that he would consider additional mitigation measures. The list of persons declaring potential conflicts is attached to these minutes as Annex III.

4. Appointment of (co-)rapporteurs

a) Appointment of (co-)rapporteurs for CLH dossiers and authorisation applications, DNEL/dose-response relationships, Article 95(3) requests and Article 77(3)(c) requests

The Secretariat collected the names of volunteers for rapporteurship for CLH dossiers and authorisation applications, as stated in the restricted room document. The Committee agreed upon the proposed appointments of the Rapporteurs for the CLH dossiers as well as the forthcoming applications for Authorisation.

5. Report from other ECHA bodies and activities

a) Report on RAC 49 action points, written procedures and update on other ECHA bodies

The Chairman informed the Committee that the action points from the previous meeting RAC-49, pending publications of three 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/50/2019/01) (see Annex IV).

The Chairman also informed the Committee that the final minutes of RAC-49 had been adopted via written procedure and were uploaded to S-CIRCABC and published on the ECHA website, and thanked those Members who had provided comments on the draft.

b) RAC work plan for all processes

The Chairman informed the meeting participants about the updated RAC work plan for 2019 and the first two quarters of 2020, covering the four processes of restriction, authorisation, harmonised classification and labelling of substances and scientific evaluations of occupational exposure limits. He informed Members that they could find the expected schedules for Restriction and Authorisation dossiers in the work plan. In addition, the scheduling to be considered for each harmonised classification and labelling (CLH) dossier are given in the relevant section in addition to those for occupational exposure limits.

c) Annual update of RAC accredited stakeholders' list

RAC discussed the Secretariat's proposal on the annual update of the Committee's list of accredited stakeholder organisations. There was no change to the current stakeholder organisations regarded as regular or occasional observers and all retained their respective status. Five new organisations interested in the work of RAC were also added to the list as occasional observers. The updated list of stakeholders (RAC/50/2019/02) was agreed by RAC. This brings the number of Regular Stakeholders to seven and the number of Occasional Stakeholders to 76; the status will be reviewed again in 2020.

The new stakeholders will be informed by the Secretariat about RAC's decision. The list will be published on ECHA's website and be applied with immediate effect following the end of the RAC-50 plenary meeting.

6. Harmonised classification and labelling (CLH)

6.1 General CLH issues

a) CLP – suggested changes in the timing of the appointment of rapporteurs

Following the presentation by the Secretariat and the discussion at RAC 49 on options how to facilitate the planning of the work of the Rapporteurs for CLH dossiers, the Chairman summarised the changes in the scheduling of the Rapporteurs' appointments (RAC/50/2019/03). All standard CLH dossiers will be subject to a call for expression of interest once they are declared in accordance (at the final submission). However, the Secretariat may identify dossiers at an early stage of intention (when discussing different aspects with the Dossier Submitters) or at first submission that are complex and that potentially require more than one plenary meeting for developing an opinion. For such cases, an early call for expression of interest will be launched to ensure that prospective Rapporteur(s) are actively involved from the very early stage of the process. In addition, the Secretariat will continue in the current practice and launch a call for expression of interest whenever new Rapporteur(s) are needed to take over dossiers already in the pipeline (pursuant to Article 17(4) of RAC RoP[1]) due to workload considerations.

6.2 CLH dossiers

A. Hazard classes for agreement without plenary debate[2] (see section B below for hazard classes for the same substances debated in plenary)

RAC reviewed an 'A-listing' of hazard classes for a range of substances and being informed by the Secretariat of the appropriate scrutiny by Rapporteurs and commenting RAC Members in each case, agreed these without plenary debate.

The Secretariat informed the Committee about the potential need to revise the justification for no classification for physical hazards for some substances on the agenda. It was brought to the Secretariat's attention in the context of the last batch of the adopted RAC opinions sent to the European Commission for the inclusion into Annex VI of the CLP Regulation (through the adaptation to technical progress, ATP) that for two substances the justification for no classification for physical hazards was not considered valid by a MSCA, which considered the

[1] The Committee may replace the rapporteur or co-rapporteur by another one of its Members at any time, if, for example, they are unable to fulfil their duties within the prescribed time limits, or if an interest that might be prejudicial to the independent consideration of a case comes to light.

[2] Following adequate scrutiny by the Rapporteur and commenting Members and taking the comments from the public consultation into account, selected hazard classes are proposed for agreement through a list ('fast-track') without further debate in the Committee.

conclusion (no classification) should have been based on the lack of data.

When following the criteria for the assessment of physical hazards, the screening procedure is applied as the first step. If the outcome of the screening is negative (=no structural alert), the conclusion is no classification (without need for further testing / investigation). In the case that the outcome of the screening is positive (=there is a structural alert), further testing needs to be applied and the testing strategy must be based on United Nations Recommendations on the Transport of Dangerous Goods (UN RTDG) or on international standards ISO 10156. Generally, the EU 'A.' test-methods are not sufficient to conclusively assess the hazard class(es).

The justification for no classification for physical hazards of two CLH dossiers on the agenda of RAC- 50 (clomazone (ISO) and ethametsulfuron-methyl (ISO)) may need to be revised, and physical hazards for these two substances were therefore taken off the 'A-listing' and brought forward for the discussion at the plenary.

1. Trinexapac-ethyl (ISO)

Trinexapac-ethyl (ISO) is an active substance used in plant protection products 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 for skin sensitisation (Skin Sens. 1B; H317) and for hazards to aquatic environment (Aquatic Chronic 1, H410, M=1).

For this meeting, only environmental hazards were scheduled and RAC proposed to classify the substance as Aquatic Chronic 1 with an M-factor of 1.

Human health hazards of trinexapac-ethyl (ISO) will be on the agenda of the following RAC plenary (November / December 2019).

B. Substances with hazard classes for agreement in plenary session

1. Methyl salicylate

The Chairman welcomed the expert accompanying the occasional stakeholder observers and the dossier submitter on webex attending the meeting and reported that methyl salicylate is an industrial chemical used as a fragrance ingredient in different fragrance products. It has no existing entry in Annex VI of the CLP Regulation. The legal deadline for the adoption of an opinion is 24 April 2020.

The Dossier Submitter (FR) proposed to classify the substance as Acute Tox. 4; H302 with an ATE (oral) of 580 mg/kg bw, Skin Sens. 1B; H317, Repr. 1B; H360D and Aquatic Chronic 3; H412. The Dossier Submitter additionally proposed no classification for effects on sexual function and fertility and for aquatic acute toxicity.

RAC agreed to the proposal by France to classify the substance as harmful if swallowed (Acute Tox. 4) but assigned an acute toxicity estimate (ATE; oral) of 890 mg/kg bw (instead of 580 mg/kg bw). RAC further agreed to classify methyl salicylate as a substance that may cause an allergic skin reaction (Skin Sens. 1B) and as harmful to aquatic life with long lasting effects (Aquatic Chronic 3). RAC also agreed with the Dossier Submitter that no classification was warranted for effects on sexual function and fertility and for aquatic acute toxicity.

RAC did not agree to classify methyl salicylate as a substance that may damage the unborn child (Repr. 1B; H360D) but instead proposed to classify the substance as suspected of damaging the

unborn child (Repr. 2; H361d), taking into account also the previous RAC opinion on salicylic acid.

Acute oral toxicity, skin sensitisation, toxicity to reproduction and environmental hazards were discussed at the plenary. A representative of industry contributed to the plenary discussion on developmental toxicity and aquatic toxicity.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

2. 4-methylpentan-2-one

The Chairman welcomed the expert accompanying the ECPA stakeholder attending the meeting reported that 4-methylpentan-2-one is an industrial chemical with wide dispersive use. The substance has an existing entry in Annex VI to the CLP Regulation and it is classified as Flam. Liq. 2; H225, Acute Tox. 4*; H332 (minimum classification), Eye Irrit. 2; H319, additional hazard statement EUH066, and STOT SE 3; H335. The legal deadline for the adoption of an opinion is 26 March 2020.

The Dossier Submitter (AT) proposed to confirm Acute Tox. 4; H332 with an ATE (inhalation) of 11 mg/L, to retain STOT SE 3; H335, Eye Irrit. 2; H319 and additional hazard statement EUH066 and to add STOT SE 3; H336 and Carc. 2; H351.

RAC agreed to the proposal by Austria to classify the substance as harmful if inhaled (Acute Tox. 4), with an acute toxicity estimate (ATE; inhalation) of 11 mg/L for vapours and to retain the classification for eye irritation (Eye Irrit. 2), and the additional hazard statement EUH066. Contrary to the proposal by Austria RAC did not agree to retain the classification for respiratory irritation (STOT SE 3). In addition, RAC agreed to the proposal by Austria to classify isobutyl methyl ketone as a substance that may cause drowsiness or dizziness (STOT SE 3) and a substance suspected of causing cancer (Carc. 2; H351).

STOT SE 3; H335 (respiratory tract irritation) and carcinogenicity were discussed at the plenary. A representative of the regular stakeholder (ECPA) contributed to the plenary discussion on STOT SE 3 for respiratory irritation and carcinogenicity.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

3. Clomazone (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that clomazone (ISO) is an active substance in plant protection products used as a herbicide. It has no existing entry in Annex VI to the CLP Regulation. The legal deadline for the adoption of an opinion is 17 May 2020.

The Dossier Submitter (DK) proposed to classify the substance as follows: Acute Tox. 4; H302, ATE=754 mg/kg bw, Acute Tox 4; H332, ATE=4.3 mg/L, Repr. 1B; H360D, Aquatic Acute 1; H400 and Aquatic Chronic 1; H410 with an M-factor of 1 for both hazards.

Selected physical hazards and all human health and environmental hazards were open for comments during the public consultation.

RAC agreed to the proposal by Denmark to classify the substance as harmful if swallowed and if inhaled (Acute Tox. 4), but with acute toxicity estimates of 767.5 mg/kg bw (ATE; oral) and of 4.85 mg/L for dusts or mists (ATE; inhalation), so not adjusting for purity. RAC also agreed

to classify clomazone (ISO) for hazards to the aquatic environment as a substance very toxic to aquatic life (Aquatic Acute 1) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1) with multiplying factors of 1 for both hazards.

Physical hazards, STOT SE and toxicity to reproduction were the hazards discussed at the plenary.

RAC agreed not to classify clomazone (ISO) for physical hazards, nor for narcotic effects (STOT SE 3).

The Committee discussed developmental toxicity but contrary to the Dossier Submitter RAC did not find the evidence sufficient for the classification. RAC found the reporting of the effects (absent bones, absence of ossification, arthrogryposis) observed in the two developmental toxicity studies available in the CLH report unclear and therefore their significance was equivocal. These developmental effects were absent in a developmental toxicity study conducted in 2018. The ECPA expert confirmed that there were some discrepancies / inaccuracies in the reporting of skeletal effects in the older developmental toxicity studies in rats (1984 and 2002) (i.e. delays in ossification were erroneously reported as absent bones). The 2018 study was made available to RAC through the public consultation and was subject to a targeted public consultation.

RAC concurred with the Dossier Submitter that the effects on fertility (slightly increased incidences of early resorptions/implantation loss in rat and rabbit but without a clear dose-relationship) were not sufficient for classification. In addition, there was no indication of treatment-related effects on lactation thus no classification was warranted for this hazard.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

4. Citric acid

The Chairman reported that citric acid is an active substance in biocidal products used as disinfectant and algaecide. It has no existing entry in Annex VI to the CLP Regulation. The legal deadline for the adoption of an opinion is 30 April 2020.

The Dossier Submitter (BE) proposed to classify the substance for skin and eye irritation (Skin. Irrit. 2; H315, Eye Irrit. 2; H319) and for respiratory irritation (STOT SE 3; H335). Selected physical hazards, human health and environmental hazards (with exception of acute inhalation toxicity, aspiration hazard and hazardous to the ozone layer) were open for comments during the public consultation.

The Committee discussed the proposal by the Dossier Submitter to classify the substance for respiratory irritation and skin irritation.

RAC agreed to the proposal by Belgium to classify citric acid as a substance causing serious eye irritation (Eye Irrit. 2) and that may cause respiratory irritation (STOT SE 3).

Contrary to the Dossier Submitter´s proposal, RAC found the evidence for skin irritation not sufficient for classification.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

5. Desmedipham (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder attending the meeting reported that desmedipham (ISO) is an active substance in plant protection products, a non-

systemic contact herbicide. The substance has an existing entry in Annex VI to the CLP Regulation and it is classified as Aquatic Acute 1; H400, M-factor of 10 and Aquatic Chronic 1; H410. The legal deadline for the adoption of an opinion is 15 May 2020.

The Dossier Submitter (FI) proposed to add Repr. 2; H361d and STOT RE 2; H373 (blood), to retain Aquatic Acute 1; H400, M-factor of 10 and Aquatic Chronic 1; H410, and to add an M-factor of 10 for chronic aquatic hazard. The Dossier Submitter additionally proposed no classification for carcinogenicity, effects on sexual function and fertility and effects on or via lactation.

RAC agreed to the proposal by Finland to classify desmedipham (ISO) as a substance suspected of damaging the unborn child (Repr. 2; H361d) and to add a multiplying M-factor of 10 to the chronic aquatic hazard. RAC also agreed with no classification for carcinogenicity, effects on sexual function and fertility and effects on or via lactation.

STOT RE, carcinogenicity and toxicity to reproduction were discussed at the plenary. A representative of the regular stakeholder (ECPA) contributed to the plenary discussion on STOT RE and toxicity for reproduction.

Contrary to the proposal by Finland, RAC did not support classification of desmedipham (ISO) as a substance that may cause damage to organs (blood) through prolonged or repeated exposure.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

6. Phenmedipham (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder attending the meeting reported that phenmedipham (ISO) is an active substance in plant protection products, a non-systemic contact herbicide. The substance has an existing entry in Annex VI to the CLP Regulation and it is classified as Aquatic Acute 1; H400 and Aquatic Chronic 1; H410. The legal deadline for the adoption of an opinion is 13 May 2020.

The Dossier Submitter (FI) proposed to add Carc. 2; H351, Repr. 2; H361d, STOT RE 2; H373 (blood), to retain Aquatic Acute 1; H400 and Aquatic Chronic 1; H410, and to add an M-factor of 10 for acute aquatic hazard and an M-factor of 10 for chronic aquatic hazard. The Dossier Submitter additionally proposed no classification for effects on sexual function and fertility and effects on or via lactation.

RAC agreed to the proposal by Finland to add multiplying M-factors of 10 to the aquatic acute and chronic classification. RAC also agreed with no classification for effects on sexual function and fertility and effects on or via lactation.

STOT RE, carcinogenicity and toxicity to reproduction were discussed at the plenary. Contrary to the proposal by Finland, RAC did not support classification of phenmedipham (ISO) as a developmental toxicant, as a carcinogen or as a substance that may cause damage to organs (blood) through prolonged or repeated exposure.

A representative of the regular stakeholder (ECPA) contributed to the plenary discussion on carcinogenicity and toxicity for reproduction.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

7. Triticonazole (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that triticonazole is an active substance in plant protection products used as a fungicide for seed treatment. It has an existing entry in Annex VI to the CLP Regulation for chronic hazards to aquatic environment (Aquatic Chronic 2; H411). The legal deadline for the adoption of an opinion is 1 May 2020.

The Dossier Submitter (AT) proposed to add classifications for repeated dose toxicity (STOT RE 2; H373), aquatic acute toxicity (Aquatic Acute 1; H400) and to modify the existing classification for aquatic chronic hazards (Aquatic Chronic 1; H410). An M-factor of 1 was proposed to be added to both hazards. All human health and environmental hazards (except aspiration hazard) were open for comments during the public consultation.

The plenary discussion focused on acute oral toxicity, STOT RE, germ cell mutagenicity, carcinogenicity and toxicity to reproduction hazards.

RAC agreed to the proposal by Austria to classify triticonazole as a substance that may cause damage to organs through prolonged or repeated exposure (STOT RE 2) and for hazards to the aquatic environment as a substance very toxic to aquatic life (Aquatic Acute 1) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1) with multiplying factors of 1 for both hazards.

In addition, contrary to the proposal by Austria, RAC supported classification of the substance as suspected of damaging fertility (Repr. 2; H361f). The ECPA expert contributed to the discussion on repeated dose toxicity and on effects on fertility and sexual function.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

8. Boric acid [1]; Diboron trioxide [2]; Tetraboron disodium heptaoxide, hydrate [3]; Disodium tetraborate, anhydrous [4]; Orthoboric acid sodium salt [5]; Disodium tetraborate decahydrate [6]; Disodium tetraborate pentahydrate [7]

The Chairman welcomed the representative of IMA-Europe (Industrial Minerals Association Europe aisbl), occasional stakeholder observer to RAC and reported that boric acid and borates are industrial chemicals used as intermediates for the production of other chemicals or as substances in the manufacture of e.g. glasses, metals, cements, lubricants, greases, inks and cleaning products. Some borates are also active substances in biocidal products as antimicrobials and wood preservative agents. Boric acid and various borates have an existing harmonised classification and labelling in Annex VI of CLP as toxic to reproduction (Repr. 1B, H360FD) and specific concentration limits (SCLs) to classify substances and mixtures varying from 3.1% to 8.5% w/w.

The legal deadline for the adoption of an opinion is 3 May 2020.

The Dossier Submitter (SE) proposed to remove the existing specific concentration limits (SCLs) and to assign a generic concentration limit (GCL) of 0.3% in order to ensure that mixtures and preparations are appropriately classified and labelled, in line with the CLP Guidance.

RAC agreed on the proposal by the Dossier Submitter and the Rapporteur to propose removing the existing SCLs for boric acid and the borates; the GCL of 0.3% will apply. All seven boron compounds were considered of medium reproductive toxicity potency and in the assessment no modifying factors were identified by RAC that would affect the concern. RAC also agreed not to

add a specific note reflecting the percentage by weight of boric acid for mixtures containing borates.

The representative of IMA-Europe raised the following concerns: (1) they consider the CLP Guidance very conservative and boundaries to place reproductive toxicants into high, medium and low potency groups rather arbitrary, (2) they recognised that borates fall into the medium potency group based on animal data but according to IMA-Europe this would not apply to humans based on the available (negative) epidemiological studies, (3) they found inconsistencies in applying modifying factors. In addition, the representative of IMA-Europe confirmed that there is no new scientific data on the borates but mentioned an ongoing scientific project (expected results in 2021).

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

9. Trifloxystrobin (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder attending the meeting and reported that trifloxystrobin (ISO) is an active substance in plant protection products used to control diseases caused by pathogenic fungi across a wide range of agricultural and horticultural crops, including cereals, vines, soft fruit, top fruit, vegetables and ornamentals, grown in open field and/or under protection. The substance has an existing entry in Annex VI to the CLP Regulation and it is classified as Skin Sens. 1; H317, Aquatic Acute 1; H400 and Aquatic Chronic 1; H410. The legal deadline for the adoption of an opinion is 28 May 2020.

The Dossier Submitter (UK) proposed to retain the aquatic hazard classes and to add M-factor 100 for Aquatic Acute hazard class (initially proposed M-factor 10, modified to 100 after the public consultation), and M-factor 10 for Aquatic Chronic hazard class. The dossier submitter additionally proposed no classification for toxicity to reproduction.

RAC agreed to the proposal by the United Kingdom to classify trifloxystrobin (ISO) as a substance very toxic to aquatic life (Aquatic Acute 1) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1) with multiplying factors of 100 and 10, respectively.

The Committee agreed in plenary on no classification for effects on sexual function and fertility and developmental toxicity. Regarding effects through or via lactation, contrary to the proposal by the Dossier Submitter, RAC supported classification of trifloxystrobin (ISO) as a substance that may cause harm to breast-fed children (Lact.; H362).

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

10. Esfenvalerate (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that esfenvalerate (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 Tox. 3*; H301, Acute Tox. 3*; H331 (minimum classifications), Skin Sens. 1; H317, Aquatic Acute 1; H400 and Aquatic Chronic 1; H410 (M-factor=10 000). The legal deadline for the adoption of an opinion is 14 May 2020.

The Dossier Submitter (UK) proposed to modify the existing acute oral and inhalation classifications (Acute Tox 3; H301, ATE(oral) = 88.5 mg/kg bw, Acute Tox 2; H330, ATE(inhalation) = 0.48mg/L), to retain classification for skin sensitisation, to retain / add M-

factors to the existing aquatic classifications and to add STOT RE (STOT RE 2; H373). The Dossier Submitter additionally proposed no classification for STOT SE, germ cell mutagenicity and carcinogenicity.

Carcinogenicity, mutagenicity, acute toxicity, STOT SE, STOT RE, skin sensitisation and hazards to the aquatic environment were open for comments during the public consultation.

RAC discussed the following hazards at the plenary: acute inhalation toxicity, STOT SE, STOT RE and carcinogenicity.

RAC agreed to classify the substance for acute toxicity through oral and inhalation routes of exposure (Acute Tox. 3 for both routes) and to add acute toxicity estimates of 88.5 mg/kg (ATE; oral) and of 0.53 mg/L for dusts or mists (ATE; inhalation), to retain the classifications for skin sensitisation (Skin Sens. 1) and for hazards to the aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1) adding a multiplying factor of 10000 to the acute hazard. RAC further agreed to the proposal by the United Kingdom to classify esfenvalerate (ISO) as a substance that may cause damage to organs through prolonged or repeated exposure (STOT RE 2), and to the no classification proposal for germ cell mutagenicity.

In addition, contrary to the proposal by the United Kingdom, RAC supported classification of esfenvalerate (ISO) as a substance that causes damage to the nervous system upon single exposure (STOT SE 1).

RAC discussed the data on carcinogenicity and noted that the incidence of Leydig cell tumours observed in the rat chronic toxicity study was slightly above the historical controls, however without statistical significance and with no clear dose response. The tumours were benign and seen in one species only. RAC concurred with the Dossier Submitter that no classification for carcinogenicity was warranted.

The ECPA expert contributed to the discussion on STOT SE and carcinogenicity.

RAC adopted the opinion by majority (pending a minority opinion by one RAC Member on STOT RE 2 classification related to mortality). The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

11.ethametsulfuron-methyl (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that ethametsulfuron-methyl (ISO) is an active substance in plant protection products used as a herbicide. The substance has no existing entry in Annex VI of the CLP Regulation. The legal deadline for the adoption of an opinion is 21 May 2020.

The Dossier Submitter (UK) proposed to classify the substance for eye irritation (Eye Irrit. 2; H319) and for hazards to the aquatic environment (Aquatic Acute 1; H400, M-factor=1 000, Aquatic Chronic 1; H410, M-factor=100). Selected physical hazards, all human health hazards (except respiratory sensitisation and aspiration hazard) and environmental hazards were open for comments during the public consultation.

RAC agreed to the proposal by the United Kingdom to classify ethametsulfuron-methyl (ISO) as a substance that causes serious eye irritation (Eye Irrit. 2) and for hazards to the aquatic environment as a substance very toxic to aquatic life (Aquatic Acute 1) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1) with multiplying factors of 1 000 and 100 respectively.

Physical hazards and toxicity to reproduction were the hazards discussed at the plenary. RAC agreed not to classify ethametsulfuron-methyl (ISO) for these endpoints.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

12.dimethomorph (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that dimethomorph (ISO) is an active substance in plant protection products used as a fungicide. It has an existing entry in Annex VI to the CLP Regulation for Aquatic Chronic 2; H411. The legal deadline for the adoption of an opinion is 21 May 2020.

The Dossier Submitter (NL) proposed to add classification for toxicity to reproduction (Repr. 1B; H360FD) and to retain the existing environmental classification (Aquatic Chronic 2; H411). The Dossier Submitter additionally proposed no classification for aquatic acute toxicity. Toxicity to reproduction and hazards to the aquatic environment were open for comments during the public consultation and were discussed at the plenary.

RAC agreed to the proposal by the Netherlands to retain the existing environmental classification (Aquatic Chronic 2, no classification for aquatic acute toxicity) and to classify dimethomorph (ISO) as a substance that may damage fertility (Repr. 1B; H360F). However, contrary to the proposal by the Netherlands, RAC did not support classification of dimethomorph as a substance that may damage the unborn child. The ECPA expert contributed to the discussion on toxicity to reproduction.

RAC adopted the opinion by majority (with a minority opinion by two RAC Members on the classification for effects on fertility and sexual function, in particular related to the adversity of effects such as onset of puberty). The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

13.Emamectin benzoate (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder attending the meeting and reported that emamectin benzoate (ISO) is an active substance in plant protection products used as an insecticide (larvicide). The substance has no existing entry in Annex VI of the CLP Regulation. The legal deadline for the adoption of an opinion is 14 February 2020.

The Dossier Submitter (NL) proposed to classify the substance as Acute Tox. 3; H301 ATE (oral) = 60 mg/kg bw, Acute Tox. 3; H311, ATE (dermal) = 500 mg/kg bw, Acute Tox. 3; H331, ATE (inhalation) = 0.663 mg/L, Eye Dam. 1; H318, STOT RE 1; H372 (nervous system), Aquatic Acute 1; H400 M-factor=10 000, and Aquatic Chronic 1; H410 M-factor=10 000 (the chronic M-factor was revised by the Dossier Submitter from 1000 to 10 000, based on the comments submitted during the public consultation).

RAC agreed to the proposal by the Netherlands to classify emamectin benzoate (ISO) as a substance which is toxic if swallowed, if inhaled and if in contact with skin (Acute Tox. 3) and to add acute toxicity estimates of 60 mg/kg bw (ATE; oral), 0.663 mg/L for dusts or mists (ATE; inhalation) and 300 mg/kg bw (ATE; dermal). RAC also agreed with the Netherlands to classify the substance as causing serious eye damage (Eye Dam. 1), as causing damage to the nervous system through prolonged or repeated exposure (STOT RE 1) and for hazards to the aquatic environment as a substance very toxic to aquatic life (Aquatic Acute 1) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1) with multiplying factors of 10 000 for both hazard classes.

In addition, contrary to the proposal by the Netherlands, RAC classified emamectin benzoate (ISO) as a substance that causes damage to the nervous system (STOT SE 1) and set specific

concentration limits for STOT RE (STOT RE 1; H372: C ≥ 5 %; STOT RE 2; H373: 0.5 % ≤ C < 5 %) for mixtures containing the substance.

Proposals for setting SCLs for STOT RE, STOT SE and toxicity to reproduction were discussed at the plenary. A representative of the regular stakeholder (ECPA) contributed to the plenary discussion on specific concentration limits for STOT RE and effects through or via lactation.

Following the discussion on reproductive toxicity, the Committee agreed on no classification for the effects on fertility and developmental toxicity. Regarding effects through or via lactation, RAC agreed on no classification because of inconclusive data.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

14.1,2-epoxy-4-epoxyethylcyclohexane

The Chairman reported that 1,2-epoxy-4-epoxyethylcyclohexane is an industrial chemical used as a chemical intermediate and a diluent for other diepoxides and epoxy resins. The substance has an existing entry in Annex VI to the CLP Regulation and it is classified as Acute Tox. 3*; H301, Acute Tox. 3*; H311, Acute Tox. 3*; H331 (*minimum classifications), and Carc. 2; H351. The legal deadline for the adoption of an opinion is 7 December 2019.

The Dossier Submitter (NL) proposed to add Repr. 1B; H360F, to modify Carc. 1B; H350, to modify Acute Tox. 4; H332, inhalation: ATE = 4.656 mg/L, to modify Acute Tox. 3; H311, dermal: ATE = 680 mg/kg bw, and to remove: Acute Tox. 3*; H301. The Dossier Submitter additionally proposed no classification for germ cell mutagenicity.

RAC agreed to the proposal by the Netherlands to classify the substance as a substance that may cause cancer (Carc. 1B; H350) and as a substance that may damage fertility (Repr. 1B; H360F).

Contrary to the proposal by the Netherlands, RAC agreed to classify the substance as harmful if swallowed (Acute Tox. 4; H302) and as toxic if inhaled (Acute Tox. 3; H331) with acute toxicity estimates of 1847 mg/kg bw (ATE; oral) and of 0.5 mg/L (dusts or mists) (ATE; inhalation) and agreed to remove the classification for acute dermal toxicity due to inconclusive data. In addition, contrary to the Dossier Submitter proposal, RAC classified 1,2-epoxy-4-epoxyethylcyclohexane as suspected of causing genetic defects (Muta 2; H341).

Acute toxicity, germ cell mutagenicity, carcinogenicity and toxicity to reproduction (fertility) were discussed at the plenary.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

15.mecoprop-P (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that mecoprop-P (ISO) is an active substance used in plant protection products as an herbicide. It has an existing entry in Annex VI to the CLP Regulation for Acute Tox. 4*; H302 (minimum classification), Eye Dam. 1; H318 and for hazards to aquatic environment as Aquatic Chronic 2; H411. The legal deadline for the adoption of an opinion is 30 January 2020.

The Dossier Submitter (UK) proposed to confirm the acute oral toxicity classification (Acute Tox. 4; H302, with an ATE(oral) of 431 mg/kg bw and to change the environmental classification

(Aquatic Chronic 3; H412). The Dossier Submitter additionally proposed no classification for STOT RE and toxicity to reproduction.

At RAC 49, the Committee agreed to the proposal by the United Kingdom to classify mecoprop-P (ISO) as harmful if swallowed (Acute Tox. 4) with an acute toxicity estimate (ATE; oral) of 431 mg/kg bw to classify and label mixtures containing the substance. AT RAC-49 RAC also agreed with no classification for STOT RE, but contrary to the proposal by the United Kingdom, RAC agreed to classify the substance as very toxic to aquatic life and very toxic to aquatic life with long lasting effects (Aquatic Acute 1 and Aquatic Chronic 1) with multiplying factors of 10 for both hazards.

At RAC-50, toxicity to reproduction was the only endpoint discussed at the plenary.

Based on the original study report provided by Industry upon RAC's request at RAC 49 and further historical control data made available by Industry, RAC discussed the effects on fertility and sexual function. RAC concurred with the Dossier Submitter that the effects in the one-generation study were not sufficient for classification, but RAC noted that the concurrent controls were exceptionally high and thus of limited use for the assessment. Combined with a two-generation study that was dosed too low, RAC concluded on no classification due to inconclusive data.

As regards developmental toxicity, RAC found the evidence in the rat and rabbit studies not sufficient for the classification RAC agreed that the mouse study (1983) already assessed in the context of another CLH dossier was not acceptable due to the absence of details and low quality of the reporting.

RAC agreed with no classification for effects on or via lactation.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

7. Restrictions

7.1 Restriction Annex XV dossiers

a) Conformity check and key issues discussion

1) Calcium cyanamide in fertilisers

The Chairman welcomed the Dossier Submitter's representatives from ECHA and an occasional stakeholder observer. He informed the participants that the restriction dossier had been submitted in July 2019.

The Dossier Submitter's representative provided an introductory presentation on the dossier. He explained that the proposal concerns the placing on the market of calcium cyanamide used as a fertiliser. The use of calcium cyanamide as a fertiliser is regulated by (EU) 2019/1009. Circa 130 000 tonnes of calcium cyanamide are manufactured annually in the EU of which about 53 000 tonnes are for use as a fertiliser. This is supplied mainly to professional farmers and estimated to be used for fertilising over 230 000 hectares. Calcium cyanamide is classified as Acute Tox. 4, STOT SE 3 and Eye Dam 1, whilst the closely related substance, cyanamide, is classified as Aquatic Chronic 3, Carc. 2, Repro. 2, Acute Tox. 3, Acute Tox. 3, STOT RE 2, Skin Corr. 1, Skin Sens. 1, Eye Dam. 1. Calcium cyanamide breaks down to calcium hydroxide and cyanamide in soil. The Dossier Submitter has found that the use of calcium cyanamide as a fertiliser (using application rates/methods recommended by the Registrant) leads to a risk that is not adequately controlled for both surface water adjacent to fertilised fields (the highest Risk Characterisation Ratios (RCRs) calculated were between approximately 2 to 494 under

reasonable worst-case assumptions) and to soil (the highest RCRs calculated were between approximately 3 to 135 under reasonable worst-case assumptions).

The Rapporteurs presented the outcome of the conformity check and the recommendations to the Dossier Submitter. They noted that this was a clear and thorough report and that all aspects of the proposal are discussed comprehensively in their view. The Rapporteurs pointed out that they had made a few recommendations for improving the dossier (on usage of Calcium cyanamide in closed system; information on enforcement, practicality and monitorability of the second restriction condition; evaluation of the data from the new mesocosm studies; information on alternatives and their associated risk).

The Committee agreed that the dossier conforms to the Annex XV requirements. In addition, the Rapporteurs presented their key issues of the restriction proposal. The Chairman informed the Committee that the public consultation on this restriction proposal will be launched on 25 September 2019 (provided that also SEAC considers it in conformity).

b) Opinion development

1) Skin sensitisers in textile

The Chairman welcomed the Dossier Submitter's representatives from France and Sweden, the SEAC Rapporteur and 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, placed on the market for the first time. There is a growing concern in the EU and worldwide regarding exposure to chemicals in textile and leather articles, such as clothes and footwear which may cause skin sensitisation in the general population. The number of individuals sensitised to chemical substances in textile and leather in the EEA31 population is estimated by the Dossier Submitter to be between 4 and 5 million, which corresponds to 0.8-1%. The number of new (incident) cases of sensitisation to chemicals in textile and leather are estimated by the Dossier Submitter to be between 45 000 and 180 000 per year, which corresponds to 0.01-0.04% of the EU28 general population annually.

The Rapporteurs presented the first draft opinion to the Committee, in which the main focus had been on the scope of the proposed restriction as well as on the identified hazard, exposure/emissions and risk. RAC agreed to include all substances having a harmonised classification as Skin Sens. 1A, 1B or 1 in the scope of the restriction and to establish a dynamic link with Annex VI of CLH. RAC also agreed to include all azo and anthraquinone dyes of concern, as well as Yellow 1, Yellow 9 and Yellow 64 in the scope of the restriction. In the absence of evidence of skin sensitisation potential, RAC did not support the inclusion of Disperse Yellow 39 and 49 in the scope of this restriction (unless reliable evidence indicating otherwise becomes available in the public consultation). RAC provisionally agreed on the elicitation for risk assessment as proposed by the Rapporteurs. For diisocyanates the Rapporteurs were asked to ensure consistency with other relevant restriction proposals.

The Rapporteurs were requested to prepare the second draft opinion, taking into account RAC 50 discussions and the RAC written consultation, by early November 2019.

2) Perfluorohexane-1-sulphhonic acid, its salts and related substances

The Chairman welcomed the RAC Rapporteurs and the Dossier Submitter representatives from Norway, informing the participants that the restriction proposal was submitted in April 2019.

The dossier proposes 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 (further referred to as PFHxS). It aims at reducing emissions of PFHxS to the environment and to prevent a possible substitution to PFHxS from PFOA when that restriction enters into force in 2020. PFHxS is widely dispersed in the environment and is found in environmental samples from all around the world (incl. remote regions) and in human blood (with long half-lives of years). Several human biomonitoring studies have demonstrated elevated levels of PFHxS in blood serum, related to exposure to PFHxS via drinking water. Furthermore, food and exposure via articles in the home environment can lead to elevated concentrations of PFHxS in human blood similar to or above those observed in occupational settings. Even though PFHxS are not registered under REACH, use and emissions in the EU has been shown and the continuous emissions of PFHxS combined with the very persistent nature of the substance is expected to lead to increasing exposure.

RAC agreed on the justification and reasons for the grouping of PFHxS, concluding that targeting use and placing on the market will reduce current emissions and prevent substitution from PFOA in 2020. Furthermore, RAC concluded on the hazard assessment with focus on minimising emissions.

RAC agreed that there is a risk that needs to be addressed, and emissions are used as a proxy for risks. Finally, RAC agreed that action is required on an EU-wide basis, and that a restriction is the most appropriate EU wide measure.

The Chairman concluded that, since RAC had made good progress in terms of agreeing on hazard and exposure related issues, the dossier will not go for full discussion in the next RAC plenary (November 2019) but a short update will be given instead on the information received from the public consultation.

3) D4/D5/D6

RAC was updated by the Rapporteurs on progress with this restriction for their information.

4) Formaldehyde and formaldehyde releasers

The Chairman welcomed the Dossier Submitter's representatives from ECHA, several stakeholders and their experts and the RAC Rapporteurs. The proposed restriction aims to restrict the placing on the market of articles releasing formaldehyde at rates resulting in concentrations greater than 0.124 mg/m^3 in a test chamber. The proposal covers articles where formaldehyde or formaldehyde-based substances (formaldehyde releasers) have been intentionally added in their production process (either as such or in mixtures) and where releases may occur as a result of off-gassing of residual formaldehyde present in the article or from degradation of the substances used in the production process. Articles for outdoor use only are not included in the restriction proposal. Articles subject to the existing restriction on CMRs in textiles, clothing and footwear (Annex XVII entry 72) as well as the use of formaldehyde and formaldehyde releasers as a biocide are exempted from the proposed restriction.

The regular stakeholder from ClientEarth and occasional stakeholders from ETRMA and EuPC, as well as the accompanying experts contributed to the discussion.

The Committee agreed with the Dossier Submitter's conclusion that mixtures and other temporary emission sources contribute to peak exposure and should not be included in the scope of the proposed restriction. RAC agreed to consider exposure from mixtures and other temporary emission sources in the uncertainty analysis only. The RAC Rapporteurs presented their

evaluation of the Dossier Submitter's risk assessment, which comprised complimentary exposure modelling based on several modified assumptions. RAC agreed with the conclusions of both the Dossier Submitter and the Rapporteurs that there is a risk to be addressed. In addition, RAC made a preliminary agreement to recommend that road vehicles/cars, railway, airplanes and passenger ships are retained in the scope of the proposed restriction for the time being, but to discuss further in the next meeting.

RAC also took note of the approach presented by the Rapporteurs to derive an emission limit for articles which is lower than the one proposed by the Dossier Submitter and on the proposal to derive an air concentration limit for vehicle cabin interiors.

The RAC Rapporteurs were requested to prepare the third draft opinion, taking into account RAC 50 discussions and the results of the public consultation, by early November 2019.

5) Microplastics

The Chairman welcomed the RAC Rapporteurs, and the Dossier Submitter representatives from ECHA, supported by experts from Sweden, several accompanying experts to regular stakeholder observers and several occasional stakeholders and their accompanying experts.

He explained that the proposal aims to restrict the use and placing on the market of intentionally added microplastics and is comprised of various measures including a ban on the placing on the market of uses of microplastics where they will inevitably be released to the environment, alongside requirements for better information in the supply chain and mandatory reporting for uses where better risk management could further reduce releases. The Dossier Submitter has estimated that approximately 36 000 tonnes of intentionally added microplastics are currently released to the environment per year. These are most likely to accumulate in terrestrial environments. Data on the toxicological and ecotoxicological effects of microplastics are limited, particularly for the terrestrial environment, which makes conventional risk assessment challenging. The restriction includes derogations for uses in certain sectors (e.g. medicinal products) and for naturally occurring and (bio)degradable polymers.

The first RAC plenary meeting discussed the proposed scope of the restriction as well as the hazard posed by microplastics. The Dossier Submitter has considered the risk assessment of microplastics using the threshold, non-threshold and 'case-by-case' approaches outlined in Annex I of REACH and considers that microplastics should be treated as a group of non-threshold substances for the purposes of risk assessment, similar to PBT/vPvB substances. Overall, the Dossier Submitter concludes that the intentional use of microplastics in products that result in releases to the environment are not adequately controlled. The scope covers a wide range of uses in consumer and professional products, including cosmetic products, detergents and maintenance products, paints and coatings, construction materials and medical products, as well as various products used in agriculture and horticulture. The proposed restriction is estimated to result in a cumulative emission reduction of approximately 400 thousand tonnes of microplastics over the 20 year period following its entry into force. This represents a reduction of 85-95% of the quantified emissions of intentionally added microplastics that would otherwise have occurred in the absence of the restriction taking effect.

The Rapporteurs then presented and RAC discussed the second draft opinion and also provided an overview of the comments received to date in the public consultation.

RAC agreed to use:

- the REACH polymer definition (Art 3[5]);
- the term 'particle';

- the proposed clarification that single molecules are not particles;
- the CLP solid definition (Annex I to the CLP Regulation);
- the proposed supplementary criteria for substances without a melting point;
- the proposed upper limit as an element of the microplastic definition i) upper limit of ≤ 5mm in all dimensions, ii) (for particles with fibre form) a length of upper limit of ≤ 15mm and length to diameter ratio of >3.

Based on a consideration of the intrinsic hazards of microplastics, RAC did not support the Dossier Submitter's proposal for setting a lower limit of 100nm for particles and 300nm for particles with fibre form, concluding that it was better not to set a lower limit, while acknowledging that this might need to be reconsidered when addressing the practicality/enforceability of the restriction proposal.

RAC also agreed that 'particles containing solid polymer' means either i) particles of any composition with a continuous solid polymer surface coating of any thickness, or ii) particles of any composition with a solid polymer content of ≥ 1% w/w'.

In addition, RAC provisionally agreed that unmodified natural polymers do not cause a concern for the environment.

RAC agreed that although there are uncertainties in the understanding of the hazard of microplastics they constitute an intrinsic hazard because i) they are associated with potential adverse effects; ii) are persistent in the environment and contribute to a long term irreversible environmental stock; and iii) are impossible to remove. RAC also agreed that a case-by-case risk assessment (Annex I, Preamble 0.10) with a non-threshold approach is the most relevant to assess the risk. Furthermore, RAC agreed that all releases should be minimised.

RAC provisionally agreed on the assumptions regarding releases, emissions, exposure route and environmental fate of microplastics. Finally, RAC agreed there is justification for action on a Union-wide basis.

The Chairman announced that due to the complexity of the dossier and the high volume of public consultation comments received, the RAC opinion deadline will be prolonged until March 2020. The Rapporteurs were requested to prepare the third draft opinion, taking into account the RAC-50 plenary presentation content and discussions, by early October 2019. In addition, a fourth version of the RAC draft opinion will be made available by early November prior to RAC-51 discussions taken into account the results of the public consultation. The RAC written commenting rounds will be launched on both versions (3 and 4) in October and November 2019.

A representative from the Commission referred to the need to further elaborate the dossier, integrating evidence collected via the public consultation in order to refine the assessment of emissions as well as possible risk management measures to prevent them. For example on uses such as infill material used in artificial turfs, that has raised stakeholder and media attention. She also recalled the idea to add a summary table with adverse effects observed, including testing conditions, as agreed in the June meeting. Finally, she acknowledged the vast amount of information received through the public consultation and the complexity of the file, which warrant extending RAC discussions.

In the margins of the plenary meeting, an ad hoc evening meeting was arranged to facilitate the discussions on the proposed biodegradation criteria with the interested members and stakeholders.

6) *N*,*N*-dimethylformamide

The Chairman welcomed the Dossier Submitter's representative from Italy (via WebEx), occasional stakeholder observers and their experts as well as the RAC Rapporteurs. The restriction dossier had been submitted by Italy in October 2018. The proposal aims to restrict the uses of the substance on its own or in mixtures in a concentration equal or greater than 0.3 %. DMF is manufactured in the EU, and used in the production of fine chemicals, pharmaceuticals, polymers, textiles, non-metallic products, perfumes/fragrances as a laboratory reagent (professional use) and as an intermediate.

The Rapporteurs presented the third draft opinion for adoption. The Committee discussed 1) evidence that the risk management measures (RMM) and operational conditions (OC) implemented and recommended by the manufacturers and/or importers are not sufficient to control the risk, 2) evidence that the existing regulatory risk management instruments are not sufficient, 3) justification whether action is required on EU-wide basis, 4) justification whether the suggested restriction is the most appropriate EU-wide measure, 5) effectiveness in reducing the identified risks, and 6) practicality of the proposed restriction, incl. enforceability, as well as 7) monitorability.

During the discussion RAC agreed that risks for workers have been identified. Therefore, action is required and should be taken on an EU-wide basis, that the restriction is an appropriate measure to adequately control the risks for workers. The Committee members did not see a need for any derogations or a longer transitional period for any sectors since according to the information provided during the public consultation, the man-made fibre industry as well as the PU coatings and membranes sector are able to comply with the proposed DNELs by using effective personal protective equipment (PPE) and by implementing job rotation. RAC members acknowledged the fact that the hierarchy of control has to be followed in the application of risk management measures and the implementation of technical RMMs to reduce exposure must be the aim for all sectors concerned.

The proposed wording of the restriction also requires use of the RAC-proposed DNEL values for the inhalation and dermal exposure in safety data sheets by those, who do not have an obligation to develop CSRs.

Regarding practicality of the restriction proposal, including enforceability, the Committee briefly discussed the advice received form the Forum. In this regard an update of the existing IOEL was discussed as an option. RAC agreed that the restriction proposal is enforceable and monitorable.

Concerning the biomonitoring of DMF, one RAC Member spoke in favour of defining a biomarker DNEL in the RAC opinion. Recognising the usefulness of such a measure but that it had not been considered by the Dossier Submitter, RAC agreed that a recommendation to the Commission on the need for a biomonitoring DNEL would be the most appropriate solution. It was also suggested that such information could be added to the recent ECHA guidance on implementing the closely related NMP restriction. Cefic expert indicated that biomonitoring is already established in many countries based on liver toxicity related OELs and could be used by industry to monitor that personal protective equipment is being correctly used.

The Committee adopted the RAC opinion by consensus. The Secretariat will forward the adopted opinion and its supporting documentation to SEAC.

7) Cobalt salts

The Chairman welcomed the Dossier Submitter's representatives from ECHA, the SEAC Rapporteurs, experts accompanying the regular Eurometaux and Cefic stakeholder observers,

as well as three occasional stakeholder observers. 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 salts are manufactured and used in the manufacture of chemicals, catalysts, battery production, surface treatment, fermentation processes, health applications, feed grade materials, biogas, etc. They are classified as Carc. 1B (inhalation), Muta. 2, Repr. 1B and skin and respiratory sensitisers. In 2016, RAC had agreed that they should be considered as genotoxic carcinogens with a non-threshold mode of action and had provided a dose-response relationship for these substances. The Chairman pointed out that at RAC 50, members are invited to decide on the limit values and the approach to take. He emphasised that due to the complexity of the discussion, the fifth draft opinion was not foreseen to be adopted at RAC 50.

The Rapporteurs explained that following RAC's decision that a mode-of-action based safe threshold could not be identified, the text of the draft opinion had been adjusted taking into account the RAC 49 discussions and now included a non- threshold approach (with a breakpoint) for the cancer effects of cobalt and a threshold approach for the non-cancer lung effects. Additionally, the last chapters of the opinion document had been drafted or revised. The Cefic industry expert had a question on the reason of the application of the assessment factor of 2.5 for "additional differences", normally referring to differences in routes of metabolism that are not relevant for metals. With regard to non-cancer lung effects, the Eurometaux invited expert asked to consider the compilation of more recent data that was provided by industry during the public consultation. The data did not show cases of cobalt related asthma at the current exposure levels. After the discussion, RAC agreed on the breakpoint of 0.5 µg Co/m³ (respirable fraction) for the carcinogenicity of cobalt (taking inflammatory effects in rats and mice as point of departure) and on 1 µg Co/m³ (inhalable fraction) for non-cancer lung effects (on the basis of human data). RAC also agreed that these levels should be used as 8 h TWA values. While the cancer risk below the breakpoint was considered by RAC to be significantly reduced, this should not be seen as a completely safe level.

RAC agreed that the restriction under REACH is currently the most appropriate EU wide measure to address the five cobalt salts although it was recognized that with an OEL it would be possible to cover all cobalt exposure sources. Therefore, RAC agreed to recommend to the Commission the setting of an OEL for all cobalt exposure sources. It was noted that the proposed restriction may need adjustments along the lines of the RAC discussion to cover:

- a different level for the "reference exposure value"
- a different "concept" for the exposure value, i.e. an 8h time weighted average (TWA) instead of the reference exposure value as an annual average.

In relation to the derogation proposal for feed additives, RAC was unable to support this from a risk perspective.

The Rapporteurs were requested to prepare the sixth draft opinion, taking into account RAC-50 discussions and the results of the public consultation, by early November 2019. RAC is expected to adopt its opinion on this dossier at RAC 51 in November/December plenary.

8. Authorisation

8.1 General authorisations issues

a) Update on incoming/future applications

The Secretariat informed the Committee that 19 new applications for authorisation were received during the July and August 2019 submission window. All of them are applications for authorisation for the uses of octylphenol ethoxylates and nonylphenol ethoxylates in the life sciences sector, including production of pharmaceutical active ingredient, formulation of reagents further incorporated in in vitro devices, their production and their use by professionals, such as laboratories, hospitals etc. Key issues in the new applications for authorisation will be discussed at RAC 51 plenary meeting in November/December 2019.

The Secretariat also informed about high numbers of opinions to be processed under the November 2019 submission window timelines.

In addition, the Secretariat presented a new opinion format for applications for authorisation. The new opinion format considers the recent European Court rulings on applications for authorisation, as well as the REACH Regulation Review issued by the European Commission. The aim of the new opinion format is to provide, in concise and consistent opinions, all relevant technical and scientific elements while leaving policy judgement to the European Commission.

b) OPnEO – consideration of approaches to risk assessment

The discussion was preceded by a presentation of the report entitled: '*Derivation of the PNEC or Dose-Response Relationship for Endocrine Disrupting Properties of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated (OPnEO)*' given by an invited expert from industry. The report was submitted by several Applicants for Authorisation as an appendix to their CSRs in order to justify adequate control. These applicants had carried out an extensive assessment of the available test data on Endocrine Disrupting effects. RAC noted that OPnEO degrades eventually to octylphenol.

RAC referred to the aquatic dataset reported in its 2014 opinion on nonylphenol in imported textiles, finding the data presented on octylphenol to be roughly comparable, i.e. the main focus was on fish life-cycle studies, although in the case of octylphenol there was also data on amphibians. During the discussion, the invited expert was asked to clarify information on a snail study which had been recently carried out by industry in support of the above report, in an attempt to identify the most sensitive taxon. He informed RAC that it was a 28 day study which did not cover the full lifecycle of the snails but did cover the reproduction phase. No consistent dose-response-relationship could be observed from the results of the test. Studies on other invertebrate taxa were seen as generally inadequate or inconclusive in the assessment of endocrine properties. The Committee was of the opinion that the data relied on in the report were not sufficiently representative of relevant taxa or compartments of the environment.

The dataset for aquatic hazards was therefore considered not to be sufficient by RAC to demonstrate a threshold and hence to derive a $PNEC_{water}$ for ED effects for OPnEO. Furthermore, RAC did not consider the proposed $PNEC_{sediment}$ and $PNEC_{soil}$ appropriate and a secondary poisoning assessment was lacking in the proposal. Negative environmental effects due to endocrine effects could not be excluded below the proposed PNEC. Therefore, adequate control based on the PNEC derivation presented in the report is not justified. RAC noted that this would have implications for several applications for authorisation of OPnEO which would be further considered as part of the evaluation by RAC and that as a consequence they would follow the socio-economic route.

8.2 Authorisation applications

a) Discussion on key issues

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

The Secretariat in cooperation with the RAC Rapporteurs provided general information regarding the new applications for authorisation and specified the identified key issues in the applications listed below:

- 146_CT_TataSteel (single use)
- 147_CTPht_AO_Bilbaina (single use)
- 148_CTPht_DEZA (single use)
- 149_CTPht_Nalon (single use)
- 150_CTPht_AO_Koppers (single use)
- 151_CTPht_AO_Rutgers (single use)
- 152_CTPht_AO_RainCarbon (single use)
- 153_CTPht_Bilbaina (single use)
- 155_OPE_Siemens_2 (five uses)
- 157_OPE_Kedrion (single use)
- 158_OPE_Sanofi (single use)
  RAC pointed that the applicant seems not to apply any RMMs to reduce emission. Methods and places used to detect concentration of OPE in waste water should be carefully scrutinised.
- 159_OPE_Merck (single use)
- 161_OPE_Swords (single use)
- 166_OPE_Ompi (single use)
- 167_OPE_Roche (single use)
- 168_OPE_Vetter (single use)
- 169_OPE_Nordisk (single use)
- 171_OPE_Wallac (two uses)
- 173_OPE_Sobi (single use)
- 174_OPE_Eli_Lilly (single use)
  RAC discussed the variation of methods used to detect OPE between different applicants and therefore, difference in detecting emissions to the environment due to different detection limits.
- 175_OPE_Rousselot (single use)
- 176_OPE_Abbott_1 (five uses)
  RAC pointed that the WWTP even specific to the hospitals (DUs) cannot efficiently prevent emission of OPE. Moreover it was not clear if all waste water containing OPE is classified as dangerous waste containing biological agents and therefore treated in relevant way.
- 177_OPE_Abbott_2 (single use)
- 178_OPE_Janssen (single use)
- 179_OPE_Octapharma (two uses)
- 181_OPE_NPE_Roche (three uses)
  One RAC member pointed that in this case the applicant decided to model what happen with the OPE and NPE in the WWTP.
- 183_NPE_GEHC_Bio-Sciences (single use)

b) Agreement on draft opinions

1) CT_TES

This is a downstream user's application for authorisation on single use of chromium trioxide submitted by Thyssenkrupp Electrical Steel GmbH and Thyssenkrupp Electrical Steel UGO S.A.S.:

Use 1: Surface treatment for the manufacture of grain-oriented electrical steel used in magnetic circuits of electric devices, in particular magnetic cores of high-performance transformers.

The use involves the use of 100-400 tonnes/year of chromium trioxide. 30-50 workers are exposed directly. The applicant requested the 11-year long review period.

The RAC Rapporteurs concluded that the risk management measures and operational conditions as proposed in the application are appropriate and effective in limiting the risk to workers and the general population, provided they are implemented as described. The highest calculated excess risk estimate for highest combined exposure is 1.56×10^{-3} over 40 years. The highest excess cancer risk calculated for humans via the environment (local scale for inhalation and oral routes, is 2.74×10^{-6} for Gelsenkirchen site, respectively 4.27×10^{-6} for Isbergues site over 70 years. The RAC Rapporteurs proposed to RAC to conclude that the estimates of excess cancer risk for workers and for indirect exposure of humans (workers and general population) via the environment calculated by the applicants allow a health impact assessment. RAC proposed recommendations for the review report. The regular stakeholder observer from ClientEarth contributed to the discussion.

RAC agreed the draft opinion as proposed by the Rapporteurs by consensus.

2) CTPht_Ariane

This is a downstream user's application for authorisation on single use of pitch, coal tar, high temperature (CTPht). The substance is used on two ArianeGroup sites.

Use 1: Industrial use of pitch, coal tar, high temp. as precursor of carbon matrix in the manufacturing of thermally and thermo-mechanically highly loaded carbon/carbon parts including nozzle throats and other critical carbon-carbon composite parts, resistant to very harsh erosion conditions, and very high temperature ranges, dedicated to high-performance civilian and military aerospace launchers. The applicant is using 8.1 tonnes/year (5.5 tonnes on site 1, 2.6 tonnes on site 2). A total of 55 workers are exposed directly. Combined risk level for workers are 1.68×10^{-7}-2.47×10^{-5} (lung cancer), 1.20×10^{-7}-1.76×10^{-5} (bladder cancer), 0-3.51×10^{-3} (skin cancer), combined risk for humans via the environment is local scale 9.21×10^{-8}-1.26×10^{-6}, regional scale 1.23×10^{-11}-1.89×10^{-10} (different cancer types). Risk values are expressed for the length of the requested 12-year review period.

The RAC Rapporteur concludes that the risk management measures and operational conditions presented in the application are appropriate and effective in limiting the risk to workers, the environment and the general population and that the description of the use provided in the CSR is sufficient to conclude on the reliability of the exposure assessment. The RAC Rapporteur also concluded that the estimates of excess cancer risk for workers and for indirect exposure of humans via environment calculated by the applicant allow a health impact assessment. The regular stakeholder observer from ClientEarth contributed to the discussion.

Following the plenary discussion the Committee agreed on the draft opinion as proposed by the RAC Rapporteur. The Committee agreed to provide risk levels over the period of 40 years for workers and 70 years for general population. RAC noted that the use applied for may result in up to approximately 1.62 kg per year emissions of the 16 PAHs to the environment. RAC agreed

to give no advice to SEAC on the length of the review period. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently.

The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

3) OPE_Boehringer

This is a downstream user's application for authorisation submitted by OPE_Boehringer by Boehringer Ingelheim Pharma GmbH & Co. KG and Boehringer Ingelheim RCV GmbH & Co KG for the following use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO).

Use 1: Use of 4-tert-OPnEO in a washing buffer to purify biological APIs (active pharmaceutical ingredients) during the production of Palivizumab and Moxetumomab pasudotox-tdfk.

The use involves the use of 0.169 tonne per year of 4-tert-OPnEO and the applicants requested the 12-year long review period.

See the Conclusions and Action Point for further details.

RAC agreed the draft opinion by consensus.

4) OPE_Ortho

This is a downstream user's application for authorisation submitted by OPE_Ortho by Ortho-Clinical Diagnostics for the following two uses of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO).

Use 1: Formulation of 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (as Triton X-100) for use in the manufacture of in vitro diagnostic VITROS® products used for infectious disease screening, endocrinology, and oncology testing.

The use 1 involves the use of < 5 kg per year Triton X-100 and the applicant requested the 12-year long review period.

See the Conclusions and Action Points for further details.

RAC agreed on the draft opinion by consensus.

Use 2: Use of 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (as Triton X-100) in two in vitro diagnostic VITROS® products used by professional diagnostic laboratories to detect antibodies to human hepatitis A virus and IgG antibodies to rubella virus.

The use 2 involves the use of < 0.5 kg Triton X-100 per year and the applicant requested 10-year long review period.

See the Conclusions and Action Points for further details

RAC agreed on the draft opinion by consensus.

9. AOB

Qualification of risks to the environment for 4-tert-octylphenol (and 4-tert-nonylphenol)

The RAC rapporteur for the OPE_Ortho and OPE_Boehringer cases presented the room document "Qualification of risks to the environment for 4-tert-OP" (RAC/50/2019/04). The rapporteur

reminded that 4-tert-OP has endocrine disrupting properties for the environment and that for the purposes of the applications for authorisation received, 4-tert-OPnEO will be treated as a non-threshold substance. The presented approach uses the environmental quality standards (EQS) established under the Water Framework Directive (WFD) for 4-tert-OP as a loose benchmark against which to compare the PECs so as to grade the likelihood of adverse effects in a qualitative way (i.e. high, moderate, low and negligible likelihood). Without a qualification of the likelihood of risks from RAC, SEAC would have to rely on release estimates as a proxy for the negative environmental impacts.

Several RAC Members supported the approach whereas other Members and STOs representing NGOs expressed concerns. One of which was that the EQS is an old reference value that does not sufficiently take into account ED properties. Several Members were of the view that the focus of RAC should be on the minimisation of releases and that RAC should not attempt to qualify risks. Also concerns about the communication of the approach were raised.

RAC decided to request further advice on the reliability of the WFD EQS and to consider whether a qualitative approach would be more appropriate. The Commission offered to seek advice from their WFD colleagues regarding the status of the octylphenol EQS.

20 September 2019

1. Part II. Conclusions and action points

2. MAIN CONCLUSIONS & ACTION POINTS

RAC 50 9-13 September 2019
16-20 September 2019
(Adopted at the meeting)

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/50/2019**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-50 minutes.
4. Appointment of (co-)rapporteurs	
a) Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, DNEL/dose-response relationships, Article 95(3) requests and Article 77(3)(c) requests	
5. Report from other ECHA bodies and activities	
a) Report on RAC 49 action points, written procedures and update on other ECHA bodies **SECR** presented document **RAC/50/2019/01.**	**SECR** to upload the document to the CIRCABC non-confidential website.
b) RAC work plan for all processes	
c) Annual update of RAC accredited stakeholders' list **RAC** agreed document **RAC/50/2019/02.**	SECR to publish the document on ECHA's website
d) General RAC procedures	
6. Harmonised classification and labelling (CLH)	
6.1 CLH dossiers	
a) CLP– suggested changes in the timing of the Appointment of rapporteurs **SECR** presented document **RAC/50/2019/03.**	**SECR** to upload the document to the CIRCABC non-confidential website.

6.2 CLH dossiers

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

  Please mention any ATE values for acute toxicity, together with the applicable route of exposure, where these were agreed by RAC through fast-tracking.

- 4-methylpentan-2-one: acute toxicity (all routes of exposure), serious eye damage / eye irritation, skin corrosion / irritation, skin sensitisation, STOT RE, STOT SE 3 (narcotic effects), germ cell mutagenicity, toxicity to reproduction, aspiration hazard, EUH066
- trinexapac-ethyl (ISO): environmental hazards
- clomazone (ISO): acute toxicity (all routes of exposure), serious eye damage /eye irritation, skin corrosion / irritation, skin or respiratory sensitisation, STOT RE, germ cell mutagenicity, carcinogenicity, aspiration hazard, environmental hazards
- citric acid: physical hazards (explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, corrosive to metals), acute toxicity (oral and dermal routes of exposure), serious eye damage / eye irritation, respiratory or skin sensitisation, germ cell mutagenicity, carcinogenicity, toxicity to reproduction, STOT RE, environmental hazards
- desmedipham (ISO): environmental hazards
- phenmedipham (ISO): environmental hazards
- triticonazole (ISO): acute toxicity (dermal and inhalation routes of exposure), STOT SE, skin corrosion/irritation, serious eye damage/irritation, respiratory sensitisation and skin sensitisation, environmental hazards
- trifloxystrobin (ISO): environmental hazards
- esfenvalerate (ISO): acute toxicity (oral route of exposure), skin sensitisation, germ cell mutagenicity, environmental hazards
- ethametsulfuron-methyl (ISO): acute toxicity (all routes of exposure), STOT SE, STOT RE, serious eye damage / eye irritation, skin corrosion /irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, environmental hazards, hazardous to the ozone layer
- emamectin benzoate (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), acute toxicity (all routes of exposure), serious eye damage / eye irritation, skin corrosion / irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, STOT RE (except SCLs), environmental hazards

- **Substances with hazard classes for agreement in plenary session**

  Please mention any ATE values for acute toxicity, together with the applicable route of exposure, where these were agreed by RAC, including those agreed through fast-tracking.

- Methyl salicylate
- 4-methylpentan-2-one
- Clomazone (ISO)
- Citric acid
- Desmedipham (ISO)

- Phenmedipham (ISO)
- Triticonazole (ISO)
- Boric acid [1]; Diboron trioxide [2]; Tetraboron disodium heptaoxide, hydrate [3]; Disodium tetraborate, anhydrous [4]; Orthoboric acid sodium salt [5]; Disodium tetraborate decahydrate [6]; Disodium tetraborate pentahydrate [7]
- Trifloxystrobin(ISO)
- Esfenvalerate (ISO)
- Ethametsulfuron-methyl (ISO)
- Dimethomorph (ISO)
- Emamectin benzoate (ISO)
- 1,2-epoxy-4-epoxyethylcyclohexane
- Mecoprop-P (ISO)

Trinexapac-ethyl (ISO)

RAC agreed on the harmonised classification and labelling as indicated in Table 2 below. [Aquatic Chronic 1, H410, M-factor=1]	**Rapporteurs** to draft the ODD for human heath part of the dossier provide it to SECR. **SECR** to launch the RAC consultation and table the dossier for the next plenary meeting (RAC 51).

1. Methyl salicylate

RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4; H302, ATE(oral) = 890 mg/kg bw, Skin Sens. 1B; H317, Repr. 2; H361d, 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.

2. 4-methylpentan-2-one

RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4; H332, ATE(inhalation) = 11 mg/L, Eye Irrit. 2; H319, STOT SE 3; H336, Carc. 2; H351, EUH066]	**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.

3. Clomazone (ISO)

RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4, H302; ATE(oral) = 767.5 mg/kg bw, Acute Tox. 4, H332; ATE(inhalation) = 4.85 mg/L (dusts or mists), Aquatic Acute 1; H400, M=1, 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 subject the final opinion to a RAC consultation for RAC to assess the revised justification for the conclusion on developmental toxicity. **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.
4. Citric acid	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Eye Irrit. 2; H319, STOT SE 3; H335]	**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.
5. Desmedipham (ISO)	
RAC adopted <u>by consensus</u> 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]	**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.
6. Phenmedipham (ISO)	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [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.
7. Triticonazole (ISO)	

RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [STOT RE 2; H373, Repr. 2; H361f, Aquatic Acute 1; H400, M=1, 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.
8. Boric acid [1]; Diboron trioxide [2]; Tetraboron disodium heptaoxide, hydrate [3]; Disodium tetraborate, anhydrous [4]; Orthoboric acid sodium salt [5]; Disodium tetraborate decahydrate [6]; Disodium tetraborate pentahydrate [7]	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [**<u>Remove</u>** specific concentration limits (SCL) for toxicity to reproduction → generic concentration limit (GCL) of 0.3% applies]	**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.
9. Trifloxystrobin (ISO)	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Lact.; H362, Aquatic Acute 1; H400, M = 100, 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.
10. Esfenvalerate (ISO)	
RAC adopted <u>by majority*</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox 3; H301, ATE(oral) = 88.5 mg/kg, Acute Tox 3; H330, ATE(inhalation) = 0.53mg/L (dusts and mists), STOT SE 1; H370 (nervous system), Skin Sens 1; H317, STOT RE 2; H373, Aquatic Acute 1; H400, M=10000, Aquatic Chronic 1; H410, M=10000] *pending minority opinion by one RAC Member on STOT RE 2 classification	**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.
11. ethametsulfuron-methyl (ISO)	

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Eye Irrit. 2; H319, Aquatic Acute 1; H400, M-factor=1000, Aquatic Chronic 1; H410, M-factor=100]	**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.
12. dimethomorph (ISO)	
RAC adopted by majority* the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360F, Aquatic Chronic 2; H411] *pending minority opinion by two RAC Members on classification for effects on fertility and sexual function	**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.
13. Emamectin benzoate (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 3; H301, ATE(oral)=60 mg/kg bw, Acute Tox. 3; H311, ATE(dermal)=300 mg/kg bw, Acute Tox. 3; H331, ATE(inhalation)=0.663 mg/L, Eye Dam. 1; H318, STOT SE 1; H370 (nervous system), STOT RE 1; H372 (nervous system), STOT RE 1; H372: C ≥ 5 %; STOT RE 2; H373: 0,5 % ≤ C < 5 %, Aquatic Acute 1; H400, M=10 000, Aquatic Chronic 1; H410, M=10 000]	**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.
14. 1,2-epoxy-4-epoxyethylcyclohexane	
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 (oral) = 1847 mg/kg, Acute Tox. 3; H331, ATE (inhalation) = 0.5 mg/L (dusts or mists), Carc. 1B; H350, Muta. 2; H341, Repr. 1B; H360F]	**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.
15. mecoprop-P (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.

[Acute Tox. 4; H302, ATE(oral)=431 mg/kg bw, Aquatic Acute 1; H400, M=10, Aquatic Chronic 1; H410, M=10]	**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.
7. Restrictions	
7.2 Restriction Annex XV dossiers	
a) Conformity check and key issues discussion	
1. Calcium cyanamide in fertilisers	
RAC agreed that the dossier conforms to the Annex XV requirements. RAC took note of the recommendations to the Dossier Submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload to S-CIRCABC.
b) Opinion development	
1. Skin sensitisers in textile	
Rapporteurs presented and RAC discussed the first draft opinion. RAC agreed to include in the scope of the restriction all substances having a harmonised classification as skin sens 1A, 1B or 1 and to establish a dynamic link with Annex VI of CLH. RAC agreed to include all azo dyes of concern, all anthraquinone dyes of concern, as well as Yellow 1, Yellow 9 and Yellow 64 into the scope of the restriction, as proposed by the Rapporteurs, based on the hazard assessment. RAC provisionally agreed on the elicitation thresholds for risk assessment as proposed by the Rapporteurs. For diisocyanates the Rapporteurs were asked to ensure consistency with the previous restriction proposal.	**SECR** to launch written consultation on the first draft opinion. **Rapporteurs** to prepare the second draft opinion, taking into account RAC-50 discussions and the RAC written consultation, by early November 2019.
2. Perfluorohexane-1-sulphhonic acid, its salts and related substances	
Rapporteurs presented and RAC discussed the first draft opinion.	**SECR** to launch written consultation on the first draft opinion.

RAC agreed on the proposed scope, justification and reasons for the grouping. Targeting use and placing on the market of PFHxS, its salts and related substances will reduce current emissions and prevent substitution from PFOA in 2020. RAC supported a broad restriction on all uses of PFHxS, its salts and related substances as well as on imported articles containing these substances. RAC concluded on the hazard assessment with focus on minimising emissions. RAC agreed to the proposed approach for exposure and emissions. RAC agreed there is a risk that needs to be addressed, and emissions are used as a proxy for risks. RAC agreed that action is required on an EU-wide basis, and that a restriction is the most appropriate EU wide measure. RAC noted that effectiveness in risk reduction is difficult to accurately estimate, i.e. the actual emission reductions.	**Rapporteurs** to prepare the second draft opinion, taking into account RAC-50 discussions and the RAC written consultation, by early November 2019.
3. D4/D5/D6	
Rapporteurs provided a status update on the dossier.	**Rapporteurs** to prepare the third draft opinion, taking into account the results of the public consultation, by early November 2019.
4. Formaldehyde and formaldehyde releasers	
Rapporteurs presented and RAC discussed the second draft opinion. RAC agreed to consider short-term exposure arising from mixtures and other temporary emission sources in the uncertainty analysis only. RAC agreed on exposure assessment and risk estimates for buildings, as proposed by the rapporteurs in the draft opinion.	**Rapporteurs** to prepare the third draft opinion, taking into account the results of the public consultation, RAC-50 discussions and RAC consultation, by early November 2019.

RAC made preliminary agreement to keep road vehicles/cars, railway, airplanes and passenger ships in the scope and leave it for further discussion. RAC took note of the approach presented by the rapporteurs on derivation of an emission limit for articles and on the proposal to derive an air concentration limit for vehicle cabin interiors.	
5. Microplastics	
Rapporteurs presented and RAC discussed the second draft opinion. RAC agreed with the proposed elements of microplastics definition to use: - the REACH polymer definition (Art 3[5]) as an element of the microplastic definition; - the term 'particle' as an element of the microplastic definition; - the proposed clarification that single molecules are not particles; - the CLP solid definition (Annex 1) as an element of the microplastic definition; - the proposed supplementary criteria for substances without a melting point; - the proposed dimensions as an element of the microplastic definition i) upper limit of ≤ 5mm in all dimensions (no lower limit), ii) (for fibres) a length of upper limit of ≤ 15mm and length to diameter ratio of >3 (no lower limit). RAC did not support Dossier Submitter's proposal for setting a lower limit of 100nm for particles and 300nm for fibres. RAC considered that it was not necessary to set a lower size limits. Furthermore, RAC agreed that 'particles containing solid polymer' means either i) particles of any composition with a continuous solid polymer surface coating of any thickness, or ii) particles of any composition with a solid polymer content of ≥ 1% w/w'. In addition, RAC provisionally agreed that unmodifed natural polymers do not cause a concern for the environment. RAC agreed that although there are uncertainties in the understanding of the hazard of microplastics they constitute an intrinsic hazard because	**Rapporteurs** to prepare the revised draft opinion, taking into account RAC-50 discussions and RAC consultation, by early October 2019. Prior to RAC-51, the Rapporteurs to prepare the fourth version of the draft opinion, by early November. **SECR** to launch written consultations on the revised versions of the draft opinions in October and November 2019.

i. they are associated with potential adverse effects; are ii. persistent in the environment and contribute to a long term irreversible environmental stock; and are iii. Impossible to remove RAC agreed that a case-by-case risk assessment (Annex I, Preamble 0.10) with a non-threshold approach is the most relevant to assess the risk. Furthermore, RAC agreed that all releases should be minimised. RAC provisionally agreed on the proposed assumptions regarding releases, emissions, exposure route and environmental fate of microplastics. Finally, RAC supported there is justification for action at Union-wide basis.	
6. *N,N*-dimethylformamide	
Rapporteurs presented and RAC discussed the third draft opinion. RAC adopted the opinion on this restriction proposal by consensus.	**Rapporteurs** to make final editorial changes (as discussed during RAC-50) 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.
7. Cobalt salts	
The Rapporteurs presented and RAC discussed the fifth draft opinion. RAC agreed on the breakpoint of 0.5 µg/m³ (respirable fraction) for the carcinogenicity of cobalt and on 1 µg/m³ (inhalable fraction) for non-cancer lung effects. RAC agreed that these levels should be used as 8 h TWA values. These should, however, not be seen as safe levels without any cancer risk. RAC agreed that there is a risk to be addressed and that action on an EU wide basis is necessary. RAC agreed that the restriction under REACH is currently the most appropriate EU wide measure to address the 5 cobalt salts although it was recognized that with an OEL it would be possible to cover all cobalt exposure sources. Therefore, RAC agreed to	**Rapporteurs** to prepare the sixth draft opinion, taking into account RAC-50 discussions and the results of the public consultation, by early November 2019.

recommend setting an OEL for all cobalt exposure sources. RAC agreed not to support the derogation for feed additives from a risk perspective.	
8. Authorisation	
8.1 General authorisation issues	
a) Update on incoming/future applications	
RAC noted the information presented by the Secretariat.	
b) OPnEO – consideration of approaches to risk assessment RAC noted the information presented by the applicants in the report Derivation of the PNEC or Dose-Response Relationship for Endocrine Disrupting Properties of 4-(1,1,3,3-Tetramethylbutyl) Phenol, Ethoxylated (OPnEO) and answers provided by industry during the plenary discussion. RAC concluded that the dataset and analysis provided in the report is **not** sufficient to derive PNEC for ED effect for 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated (OPnEO). Therefore, the applications for authorisation via the adequate control route based on PNEC derivation presented in the report is not justified.	**SECR** to inform all applicants about the RAC conclusions. **Rapporteurs** together with **SECR** to apply agreed conclusions in relevant draft opinions.
8.2 Authorisation applications	
a) Discussion on key issues	
1. 27 applications for authorisation from May 2019 submission window (OPE/NPE, CTPht, Cr(VI)) RAC discussed the key issues in the twenty seven applications for authorisation.	**SECR** to inform SEAC about the outcome of the discussion.
b) Agreement on draft opinions	
1. CT_TES (1 use) RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC considers that the risk management measures and operational conditions as proposed in the	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the applicant for commenting.

application are appropriate and effective in limiting the risk to workers and the general population, provided they are implemented as described. RAC considers that the estimates of excess cancer risk for workers and for indirect exposure of humans (workers and general population) via Env. calculated by the applicants allow a health impact assessment. RAC notes that without any proper risk characterisation no conclusion can be drawn with regard to the risk reduction of the alternatives. RAC agreed to give no advice to SEAC on the length of the review period. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently.	
4. CTPht_Ariane (1 use) RAC agreed on the draft opinion as proposed by the Rapporteur. RAC considered that the risk management measures and operational conditions presented in the application are appropriate and effective in limiting the risk to workers, the environment and the general population. RAC considers that the description of the use provided in the CSR is sufficient to conclude on the reliability of the exposure assessment. RAC considers that the estimates of excess cancer risk for workers and for indirect exposure of humans via environment calculated by the applicant allow a health impact assessment. RAC agreed to provide risk levels over the period of 40 years for workers and 70 years for general population. RAC noted that the use applied for may result in up to approximately 1.62 kg per year emissions of the 16 PAHs to the environment. RAC agreed to give no advice to SEAC on the length of the review period. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently.	**Rapporteur** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.
5. OPE_Boehringer (1 use)	

RAC agreed on the draft opinion as proposed by the Rapporteurs but RAC decided to remove the comparison to the EQS. RAC concluded, in accordance with Annex I of the REACH Regulation, that for the purposes of the assessment of this application it was not possible to determine PNEC for the endocrine disrupting properties for the environment of the substance. RAC is of the view that the applicants have demonstrated that releases to environmental compartments have been prevented or minimised as far as technically and practically possible. RAC is of the view that the likelihood of adverse effects can be considered negligible. The use applied for may result in up to approximately 45 mg per year emissions of the substance to the environment. 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. RAC did not evaluate the potential risk of alternatives, following the SEAC conclusion that currently there are no technically and economically feasible alternatives available for the applicant. No conditions or monitoring arrangements are proposed. RAC agreed to give no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicants for commenting.
6. OPE_Ortho (2 uses) RAC concluded, in accordance with Annex I of the REACH Regulation, that for the purposes of the assessment of this application it was not possible to determine PNEC for the endocrine disrupting properties for the environment of the substance. **Use 1**: RAC agreed on the draft opinion as proposed by the Rapporteurs but RAC decided to remove statements on the qualification of risks and reference to EQS. Based on the OCs & RMMs in the ES, the total amount of 4-tert-OPnEO used per year, the partly closed system production process and incineration of solid and liquid wastes, RAC is of the view that the applicant has demonstrated that releases to environmental compartments have been prevented	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the applicants for commenting.

or minimised as far as technically and practically possible. Based on the exposure estimates presented by the applicant, adverse effects to the local environment may result from the use applied for. 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 use applied for may result in up to approximately 5.4 g/year (2017) / 31 g/year (2032) emissions of the substance to the environment. RAC did not evaluate the potential risk of alternatives as it is not relevant, since Use 1 covers only formulation. No conditions or monitoring arrangements are proposed. RAC makes a recommendation for the review period to assess feasibility to collect the remaining liquid wastes. RAC agreed to give no advice to SEAC on the length of the review period. **Use 2:** RAC agreed on the draft opinion and concluded that a condition to collect liquid waste for adequate treatment is technically and practically possible. Based on the OCs & RMMs in the ES, notably the absence of a requirement to collect liquid wastes for adequate treatment, RAC is of the view that the applicant has not demonstrated that releases to environmental compartments have been prevented or minimised as far as technically and practically possible. Based on the exposure estimates presented by the applicant, adverse effects to the local environment may result from the use applied for. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk to the environment. The use applied for may result in up to approximately 24.5 g/year (2017) /<100 g/year (2030) emissions of the substance to the environment. RAC did not evaluate the potential risk of alternatives as no technically and economically feasible alternatives are available before the Sunset Date.	

RAC decided to provide additional conditions for authorisation and review period. *<u>Condition for authorisation</u>* *All liquid waste shall be collected for adequate treatment that minimises releases to environmental compartments as far as technically and practically possible.* *<u>Recommendation for review report</u>* *Applicant shall report on a new representative survey of their DUs about their behaviour to collect liquid waste for adequate treatment, and which treatment methods are applied.* RAC agreed to give no advice to SEAC on the length of the review period.	
9. AOB	
Qualification of risks to the environment for 4-tert-OP [and 4-tert-NP] RAC discussed the room document Qualification of risks to the environment for 4-tert-OP (RAC/50/2019/04). RAC supported in principle the idea of to provide an indication to SEAC on the likelihood of effects. However, RAC decided to look for further advice on the WFD EQS and then to consider the matter further and examine a more appropriate wording. RAC requested the ECHA Secretariat to revise the document.	**SECR** to revise the document according to the discussion and distribute it to **RAC** and to the **Commission.** **Commission** to provide comments on the revised document. **SECR** to launch RAC consultation on the revised document. **SECR** to schedule the document for discussion and agreement.
10. 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-50

1. Methyl salicylate
2. 4-methylpentan-2-one
3. Clomazone (ISO)
4. Citric acid
5. Desmedipham (ISO)
6. Phenmedipham (ISO)
7. Triticonazole (ISO)
8. Boric acid and other borates
9. Trifloxystrobin (ISO)
10. Esfenvalerate (ISO)
11. Ethametsulfuron-methyl (ISO)
12. Dimethomorph (ISO)
13. Emamectin benzoate (ISO)
14. 1,2-epoxy-4-epoxyethylcyclohexane
15. Mecoprop-P (ISO)

Table 2

1. **Trinexapac-ethyl (ISO)**

Table 1

1. Methyl salicylate

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	methyl salicylate	204-317-7	119-36-8	Repr. 1B Acute Tox. 4 Skin Sens. 1B Aquatic Chronic 3	H360D H302 H317 H412	GHS07 GHS08 Dgr	H360D H302 H317 H412		oral: ATE = 580 mg/kg bw	
RAC opinion	TBD	methyl salicylate	204-317-7	119-36-8	Repr. 2 Acute Tox. 4 Skin Sens. 1B Aquatic Chronic 3	H361d H302 H317 H412	GHS07 GHS08 Wng	H361d H302 H317 H412		oral: ATE = 890 mg/kg bw	
Resulting Annex VI entry if agreed by COM	TBD	methyl salicylate	204-317-7	119-36-8	Repr. 2 Acute Tox. 4 Skin Sens. 1B Aquatic Chronic 3	H361d H302 H317 H412	GHS07 GHS08 Wng	H361d H302 H317 H412		oral: ATE = 890 mg/kg bw	

2. 4-methylpentan-2-one

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	606-004-00-4	4-methylpentan-2-one; isobutyl methyl ketone	203-550-1	108-10-1	Flam. Liq. 2 Acute Tox. 4* Eye Irrit. 2 STOT SE 3	H225 H332 H319 H335	GHS02 GHS07 Dgr	H225 H332 H319 H335	EUH066		
Dossier submitters proposal	606-004-00-4	4-methylpentan-2-one; isobutyl methyl ketone	203-550-1	108-10-1	**Retain** Eye Irrit. 2 STOT SE 3 **Modify** Acute Tox. 4 **Add** STOT SE 3 Carc. 2	**Retain** H319 H335 H332 **Modify** H332 **Add** H336 H351	**Retain** GHS07 Dgr **Add** GHS08	**Retain** H319 H335 H332 **Modify** H332 **Add** H336 H351	**Retain** EUH066	**Add** Inhalation: ATE = 11 mg/L (vapours)	
RAC opinion	606-004-00-4	4-methylpentan-2-one; isobutyl methyl ketone	203-550-1	108-10-1	**Retain** Eye Irrit. 2 **Modify** Acute Tox. 4 **Add** STOT SE 3 Carc. 2 **Remove** STOT SE3	**Retain** H319 H332 **Add** H336 H351 **Remove** H335	**Retain** GHS07 Dgr **Add** GHS08	**Retain** H319 H332 **Add** H336 H351 **Remove** H335	**Retain** EUH066	**Add** Inhalation: ATE = 11 mg/L (vapours)	
Resulting Annex VI entry if agreed by COM	606-004-00-4	4-methylpentan-2-one; isobutyl methyl ketone	203-550-1	108-10-1	Flam. Liq. 2 Carc. 2 Acute Tox. 4 Eye Irrit. 2 STOT SE 3	H225 H351 H332 H319 H336	GHS02 GHS07 GHS08 Dgr	H225 H351 H332 H319 H336	EUH066	Inhalation: ATE = 11 mg/L (vapours)	

3. Clomazone (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	clomazone (ISO); 2-(2-chlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one	-	81777-89-1	Repr. 1B Acute Tox. 4 Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H360D H332 H302 H400 H410	GHS07 GHS08 GHS09 Dgr	H360D H332 H302 H410		inhalation: ATE = 4.3 mg/L (dusts or mists) oral: ATE = 754 mg/kg bw M = 1 M = 1	
RAC opinion	TBD	clomazone (ISO); 2-(2-chlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one	-	81777-89-1	Acute Tox. 4 Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H332 H302 H400 H410	GHS07 GHS09 Wng	H332 H302 H410		inhalation: ATE = 4.85 mg/L (dusts or mists) oral: ATE = 767.5 mg/kg M = 1 M = 1	
Resulting Annex VI entry if agreed by COM	TBD	clomazone (ISO); 2-(2-chlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one	-	81777-89-1	Acute Tox. 4 Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H332 H302 H400 H410	GHS07 GHS09 Wng	H332 H302 H410		inhalation: ATE = 4.85 mg/L (dusts or mists) oral: ATE = 767.5 mg/kg M = 1 M = 1	

4. Citric acid

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	citric acid	201-069-1	77-92-9	Skin Irrit. 2 Eye Irrit. 2 STOT SE 3	H315 H319 H335	GHS07 Wng	H315 H319 H335			
RAC opinion	TBD	citric acid	201-069-1	77-92-9	Eye Irrit. 2 STOT SE 3	H319 H335	GHS07 Wng	H319			
Resulting Annex VI entry if agreed by COM	TBD	citric acid	201-069-1	77-92-9	Eye Irrit. 2 STOT SE 3	H319 H335	GHS07 Wng	H319 H335			

5. Desmedipham (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	616-113-00-9	desmedipham (ISO); ethyl 3-phenylcarbamoyloxyphenyl carbamate	237-198-5	13684-56-5	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=10	
Dossier submitters proposal	616-113-00-9	desmedipham (ISO); ethyl 3-phenylcarbamoyloxyphenyl carbamate	237-198-5	13684-56-5	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Repr. 2 STOT RE 2	**Retain** H400 H410 **Add** H361d H373 (blood)	**Retain** GHS09 Wng **Add** GHS08	**Retain** H410 **Add** H361d H373 (blood)		**Modify** M=10 M=10	
RAC opinion	616-113-00-9	desmedipham (ISO); ethyl 3-phenylcarbamoyloxyphenyl carbamate	237-198-5	13684-56-5	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Repr. 2	**Retain** H400 H410 **Add** H361d	**Retain** GHS09 Wng **Add** GHS08	**Retain** H410 **Add** H361d		**Modify** M=10 M=10	
Resulting Annex VI entry if agreed by COM	616-113-00-9	desmedipham (ISO); ethyl 3-phenylcarbamoyloxyphenyl carbamate	237-198-5	13684-56-5	Repr. 2 Aquatic Acute 1 Aquatic Chronic 1	H361d H400 H410	GHS08 GHS09 Wng	H361d H410		 M=10 M=10	

6. Phenmedipham (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	616-106-00-0	phenmedipham (ISO); methyl 3-(3-methylcarbaniloyloxy)carbanilate	237-199-0	13684-63-4; (35067-67-5)	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410			
Dossier submitters proposal	616-106-00-0	phenmedipham (ISO); methyl 3-(3-methylcarbaniloyloxy)carbanilate	237-199-0	13684-63-4; (35067-67-5)	**Add** Carc. 2 Repr. 2 STOT RE 2 **Retain** Aquatic Acute 1 Aquatic Chronic 1	**Add** H351 H361d H373 (blood) **Retain** H400 H410	**Add** GHS08 **Retain** GHS09 Wng	**Add** H351 H361d H373 (blood) **Retain** H410		**Add** M=10 M=10	
RAC opinion	616-106-00-0	phenmedipham (ISO); methyl 3-(3-methylcarbaniloyloxy)carbanilate	237-199-0	13684-63-4; (35067-67-5)	**Retain** Aquatic Acute 1 Aquatic Chronic 1	**Retain** H400 H410	**Retain** GHS09 Wng	**Retain** H410		**Add** M=10 M=10	
Resulting Annex VI entry if agreed by COM	616-106-00-0	phenmedipham (ISO); methyl 3-(3-methylcarbaniloyloxy)carbanilate	237-199-0	13684-63-4; (35067-67-5)	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=10 M=10	

7. Triticonazole (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	613-282-00-0	triticonazole (ISO); (*RS*)-(*E*)-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-methyl)cyclopentanol	-	131983-72-7	Aquatic Chronic 2	H411	GHS09	H411			
Dossier submitter's proposal	613-282-00-0	triticonazole (ISO); (*RS*)-(*E*)-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-methyl)cyclopentanol	-	138182-18-0	**Add** STOT RE 2 Aquatic Acute 1 **Modify** Aquatic Chronic 1	**Add** H373 H400 **Modify** H410	**Add** GHS08 Wng **Retain** GHS09	**Add** H373 **Modify** H410		**Add** M=1 M=1	
RAC opinion	613-282-00-0	triticonazole (ISO); (*RS*)-(*E*)-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-methyl)cyclopentanol	-	138182-18-0	**Add** Repr. 2 STOT RE 2 Aquatic Acute 1 **Modify** Aquatic Chronic 1	**Add** H361f H373 H400 **Modify** H410	**Add** GHS08 Wng **Retain** GHS09	**Add** H361f H373 **Modify** H410		**Add** M=1 M=1	
Resulting Annex VI entry if agreed by COM	613-282-00-0	triticonazole (ISO); (*RS*)-(*E*)-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-methyl)cyclopentanol	-	138182-18-0	Repr. 2 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H361f H373 H400 H410	GHS08 GHS09 Wng	H361f H373 H410		M=1 M=1	

8. Boric acid and borates

8.1 Boric acid

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	005-007-00-2	boric acid [1] boric acid [2]	233-139-2 [1] 234-343-4 [2]	10043-35-3 [1] 11113-50-1 [2]	Repr. 1B	H360FD	GHS08 Dgr	H360FD		Repr. 1B; H360FD: C ≥ 5,5%	
Dossier submitters proposal	005-007-00-2	boric acid [1] boric acid [2]	233-139-2 [1] 234-343-4 [2]	10043-35-3 [1] 11113-50-1 [2]	**Retain** Repr. 1B	**Retain** H360FD	**Retain** GHS08 Dgr	**Retain** H360FD		**Remove** Repr. 1B; H360FD: C ≥ 5,5%	
Resulting Annex VI entry if agreed by RAC and COM	005-007-00-2	boric acid [1] boric acid [2]	233-139-2 [1] 234-343-4 [2]	10043-35-3 [1] 11113-50-1 [2]	Repr. 1B	H360FD	GHS08 Dgr	H360FD			

8.2 Diboron trioxide

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	005-008-00-8	diboron trioxide	215-125-8	1303-86-2	Repr. 1B	H360FD	GHS08 Dgr	H360FD		Repr. 1B; H360FD: C ≥ 3,1%	
Dossier submitters proposal	005-008-00-8	diboron trioxide	215-125-8	1303-86-2	**Retain** Repr. 1B	**Retain** H360FD	**Retain** GHS08 Dgr	**Retain** H360FD		**Remove** Repr. 1B; H360FD: C ≥ 3,1%	
Resulting Annex VI entry if agreed by RAC and COM	005-008-00-8	diboron trioxide	215-125-8	1303-86-2	Repr. 1B	H360FD	GHS08 Dgr	H360FD			

8.3 tetraboron disodium heptaoxide, hydrate [1], disodium tetraborate, anhydrous [2], orthoboric acid, sodium salt [3]

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	005-011-00-4	tetraboron disodium heptaoxide, hydrate [1] disodium tetraborate, anhydrous [2] orthoboric acid, sodium salt [3]	235-541-3 [1] 215-540-4 [2] 237-560-2 [3]	12267-73-1 [1] 1330-43-4 [2] 13840-56-7 [3]	Repr. 1B	H360FD	GHS08 Dgr	H360FD		Repr. 1B; H360FD: ≥ 4,5%	
Dossier submitters proposal	005-011-00-4	tetraboron disodium heptaoxide, hydrate [1] disodium tetraborate, anhydrous [2] orthoboric acid, sodium salt [3]	235-541-3 [1] 215-540-4 [2] 237-560-2 [3]	12267-73-1 [1] 1330-43-4 [2] 13840-56-7 [3]	**Retain** Repr. 1B	**Retain** H360FD	**Retain** GHS08 Dgr	**Retain** H360FD		**Remove** Repr. 1B; H360FD: ≥ 4,5%	
Resulting Annex VI entry if agreed by RAC and COM	005-011-00-4	tetraboron disodium heptaoxide, hydrate [1] disodium tetraborate, anhydrous [2] orthoboric acid, sodium salt [3]	235-541-3 [1] 215-540-4 [2] 237-560-2 [3]	12267-73-1 [1] 1330-43-4 [2] 13840-56-7 [3]	Repr. 1B	H360FD	GHS08 Dgr	H360FD			

8.4 disodium tetraborate decahydrate

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	005-011-01-1	disodium tetraborate decahydrate	215-540-4	1303-96-4	Repr. 1B	H360FD	GHS08 Dgr	H360FD		Repr. 1B; H360FD: ≥ 8,5%	
Dossier submitters proposal	005-011-01-1	disodium tetraborate decahydrate	215-540-4	1303-96-4	**Retain** Repr. 1B	**Retain** H360FD	**Retain** GHS08 Dgr	**Retain** H360FD		**Remove** Repr. 1B; H360FD: ≥ 8,5%	
Resulting Annex VI entry if agreed by RAC and COM	005-011-01-1	disodium tetraborate decahydrate	215-540-4	1303-96-4	Repr. 1B	H360FD	GHS08 Dgr	H360FD			

8.5 disodium tetraborate pentahydrate

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	005-011-02-9	disodium tetraborate pentahydrate	215-540-4	12179-04-3	Repr. 1B	H360FD	GHS08 Dgr	H360FD		Repr. 1B; H360FD: ≥ 6,5%	
Dossier submitters proposal	005-011-02-9	disodium tetraborate pentahydrate	215-540-4	12179-04-3	**Retain** Repr. 1B	**Retain** H360FD	**Retain** GHS08 Dgr	**Retain** H360FD		**Remove** Repr. 1B; H360FD: ≥ 6,5%	
Resulting Annex VI entry if agreed by RAC and COM	005-011-02-9	disodium tetraborate pentahydrate	215-540-4	12179-04-3	Repr. 1B	H360FD	GHS08 Dgr	H360FD			

9. Trifloxystrobin (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	607-424-00-0	trifloxystrobin (ISO); (*E*,*E*)-α-methoxyimino-{2-[[[[1- [3-(trifluoromethyl)phenyl]ethylidene]amino]oxy]methyl]benzeneacetic acid methyl ester	–	141517-21-7	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H317 H400 H410	GHS07 GHS09 Wng	H317 H410			
Dossier submitters proposal	607-424-00-0	trifloxystrobin (ISO); methyl (*E*)-methoxyimino-{(*E*)-α-[1-(α,α,α-trifluoro-*m*-tolyl)ethylideneaminooxy]-*o*-tolyl}acetate	–	141517-21-7	**Retain** Aquatic Acute 1 Aquatic Chronic 1	**Retain** H400 H410	**Retain** GHS09 Wng	**Retain** H410		**Add** M=10 M=10	
RAC opinion	607-424-00-0	trifloxystrobin (ISO); methyl (*E*)-methoxyimino-{(*E*)-α-[1-(α,α,α-trifluoro-*m*-tolyl)ethylideneaminooxy]-*o*-tolyl}acetate	–	141517-21-7	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Lact.	**Retain** H400 H410 **Add** H362	**Retain** GHS09 Wng	**Retain** H410 **Add** H362		**Add** M=100 M=10	
Resulting Annex VI entry if agreed by COM	607-424-00-0	trifloxystrobin (ISO); methyl (*E*)-methoxyimino-{(*E*)-α-[1-(α,α,α-trifluoro-*m*-tolyl)ethylideneaminooxy]-*o*-tolyl}acetate	–	141517-21-7	Lact. Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H362 H317 H400 H410	GHS07 GHS09 Wng	H362 H317 H410		M=100 M=10	

10. Esfenvalerate (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	608-058-00-4	esfenvalerate (ISO); (*S*)-α-cyano-3-phenoxybenzyl-(*S*)-2-(4-chlorophenyl)-3-methylbutyrate	-	66230-04-4	Acute Tox. 3* Acute Tox. 3* Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H331 H301 H317 H400 H410	GHS06 GHS09 Dgr	H331 H301 H317 H410		M=10000	
Dossier submitters proposal	608-058-00-4	esfenvalerate (ISO); (*S*)-α-cyano-3-phenoxybenzyl-(*S*)-2-(4-chlorophenyl)-3-methylbutyrate	-	66230-04-4	**Retain** Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1 **Add** STOT RE 2 **Modify** Acute Tox. 3 Acute Tox. 2	**Retain** H301 H317 H400 H410 **Add** H373 **Modify** H330	**Retain** GHS06 GHS09 Dgr **Add** GHS08	**Retain** H301 H317 H410 **Add** H373 **Modify** H330		**Retain** M=10000 **Add** oral: ATE = 88.5 mg/kg bw inhalation: ATE = 0.48 mg/L (dusts or mists) M=10000	
RAC opinion	608-058-00-4	esfenvalerate (ISO); (*S*)-α-cyano-3-phenoxybenzyl-(*S*)-2-(4-chlorophenyl)-3-methylbutyrate	-	66230-04-4	**Retain** Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1 **Add** STOT SE 1 STOT RE 2 **Modify** Acute Tox. 3 Acute Tox. 3	**Retain** H301 H331 H317 H400 H410 **Add** H370 (nervous system) H373	**Retain** GHS06 GHS09 Dgr **Add** GHS08	**Retain** H301 H331 H317 H410 **Add** H370 (nervous system) H373		**Retain** M=10000 **Add** oral: ATE = 88.5 mg/kg bw inhalation; ATE = 0.53 mg/L (dusts or mists) M=10000	
Resulting Annex VI entry if agreed by COM	608-058-00-4	esfenvalerate (ISO); (*S*)-α-cyano-3-phenoxybenzyl-(*S*)-2-(4-chlorophenyl)-3-methylbutyrate	-	66230-04-4	Acute Tox. 3 Acute Tox. 3 STOT SE 1 STOT RE 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H331 H301 H370 (nervous system) H373 H317 H400 H410	GHS06 GHS08 GHS09 Dgr	H331 H301 H370 (nervous system) H373 H317 H410		oral: ATE = 88.5 mg/kg bw inhalation: ATE = 0.53 mg/L (dusts or mists) M=10000 M=10000	

11. Ethametsulfuron-methyl (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	ethametsulfuron-methyl (ISO); methyl 2-[(4-ethoxy-6-methylamino-1,3,5-triazin-2-yl)carbamoylsulfamoyl]benzoate	-	97780-06-8	Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H319 H400 H410	GHS07 GHS09 Wng	H319 H410		M = 1000 M = 100	
RAC opinion	TBD	ethametsulfuron-methyl (ISO); methyl 2-[(4-ethoxy-6-methylamino-1,3,5-triazin-2-yl)carbamoylsulfamoyl]benzoate	-	97780-06-8	Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H319 H400 H410	GHS07 GHS09 Wng	H319 H410		M=1000 M=100	
Resulting Annex VI entry if agreed by COM	TBD	ethametsulfuron-methyl (ISO); methyl 2-[(4-ethoxy-6-methylamino-1,3,5-triazin-2-yl)carbamoylsulfamoyl]benzoate	-	97780-06-8	Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H319 H400 H410	GHS07 GHS09 Wng	H319 H410		M=1000 M=100	

12. Dimethomorph (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	613-102-00-0	dimethomorph (ISO); 4-(3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)acryloyl) morpholine	404-200-2	110488-70-5	Aquatic Chronic 2	H411	GHS09	H411			
Dossier submitters proposal	613-102-00-0	dimethomorph (ISO); (*E,Z*)-4-(3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)acryloyl) morpholine	404-200-2	110488-70-5	**Retain** Aquatic Chronic 2 **Add** Repr. 1B	**Retain** H411 **Add** H360FD	**Retain** GHS09 **Add** GHS08 Dgr	**Retain** H411 **Add** H360FD			
RAC opinion	613-102-00-0	dimethomorph (ISO); (*E,Z*)-4-(3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)acryloyl) morpholine	404-200-2	110488-70-5	**Retain** Aquatic Chronic 2 **Add** Repr. 1B	**Retain** H411 **Add** H360F	**Retain** GHS09 **Add** GHS08 Dgr	**Retain** H411 **Add** H360F			
Resulting Annex VI entry if agreed by COM	613-102-00-0	dimethomorph (ISO); (*E,Z*)-4-(3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)acryloyl) morpholine	404-200-2	110488-70-5	Repr. 1B Aquatic Chronic 2	H360F H411	GHS08 GHS09 Dgr	H360F H411			

13. Emamectin benzoate (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	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	614-RST-VW-Y	emamectin benzoate (ISO); (4''R)-4''-deoxy-4''-(methylamino) avermectin B1 benzoate	-	155569-91-8	Acute Tox. 3 Acute Tox. 3 Acute Tox. 3 STOT RE 1 Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	H331 H311 H301 H372 (nervous system) H318 H400 H410	GHS05 GHS06 GHS08 GHS09 Dgr	H331 H311 H301 H372 (nervous system) H318 H410		Inhalation: ATE = 0,663 mg/l (dusts or mists) Dermal: ATE = 500 mg/kg bw Oral: ATE = 60 mg/kg bw M=10000 M=10000	
RAC opinion	614-RST-VW-Y	emamectin benzoate (ISO); (4''R)-4''-deoxy-4''-(methylamino) avermectin B1 benzoate	-	155569-91-8	Acute Tox. 3 Acute Tox. 3 Acute Tox. 3 STOT SE 1 STOT RE 1 Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	H331 H311 H301 H370 (nervous system) H372 (nervous system) H318 H400 H410	GHS05 GHS06 GHS08 GHS09 Dgr	H331 H311 H301 H370 (nervous system) H372 (nervous system) H318 H410		inhalation: ATE = 0,663 mg/l (dusts or mists) dermal: ATE = 300 mg/kg bw oral: ATE = 60 mg/kg bw STOT RE 1; H372: C ≥ 5 %; STOT RE 2; H373: 0,5 % ≤ C < 5 % M=10000 M=10000	
Resulting Annex VI entry if agreed by COM	614-RST-VW-Y	emamectin benzoate (ISO); (4''R)-4''-deoxy-4''-(methylamino) avermectin B1 benzoate	-	155569-91-8	Acute Tox. 3 Acute Tox. 3 Acute Tox. 3 STOT SE 1 STOT RE 1 Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	H331 H311 H301 H370 (nervous system) H372 (nervous system) H318	GHS05 GHS06 GHS08 GHS09 Dgr	H331 H311 H301 H370 (nervous system) H372 (nervous system) H318		inhalation: ATE = 0,663 mg/l (dusts or mists) dermal: ATE = 300 mg/kg bw oral: ATE =	

						H400 H410		H410		60 mg/kg bw STOT RE 1; H372: C ≥ 5 %; STOT RE 2; H373: 0,5 % ≤ C < 5 % M=10000 M=10000	

14. 1,2-epoxy-4-epoxyethylcyclohexane

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 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	603-066-00-4	1,2-epoxy-4-epoxyethylcyclohexane; 4-vinylcyclohexene diepoxide	203-437-7	106-87-6	Carc. 2 Acute Tox. 3* Acute Tox. 3* Acute Tox. 3*	H351 H331 H311 H301	GHS08 GHS06 Dgr	H351 H331 H311 H301			
Dossier submitters proposal	603-066-00-4	7-oxa-3-oxiranylbicyclo[4.1.0]heptane; 1,2-epoxy-4-epoxyethylcyclohexane; 4-vinylcyclohexene diepoxide	203-437-7	106-87-6	**Add** Repr. 1B **Modify** Carc. 1B Acute Tox. 4 Acute Tox. 3 **Remove** Acute Tox. 3	**Retain** H311 **Add** H360F **Modify** H350 H332 **Remove** H301	**Retain** GHS08 GHS06 Dgr	**Retain** H311 **Add** H360F **Modify** H350 H332 **Remove** H301		**Add:** inhalation: ATE = 4.656 mg/L dermal: ATE = 680 mg/kg bw	
RAC opinion	603-066-00-4	7-oxa-3-oxiranylbicyclo[4.1.0]heptane; 1,2-epoxy-4-epoxyethylcyclohexane; 4-vinylcyclohexene diepoxide	203-437-7	106-87-6	**Add** Repr. 1B Muta. 2 **Modify** Carc. 1B Acute Tox. 3 Acute Tox. 4 **Remove** Acute Tox. 3*	**Retain** H331 **Add** H360F H341 **Modify** H350 H302 **Remove** H311	**Retain** GHS08 GHS06 Dgr	**Retain** H331 **Add** H360F H341 **Modify** H350 H302 **Remove** H311		**Add:** inhalation: ATE = 0.5 mg/L (dusts or mists) oral: ATE = 1847 mg/kg bw	
Resulting Annex VI entry if agreed by COM	603-066-00-4	7-oxa-3-oxiranylbicyclo[4.1.0]heptane; 1,2-epoxy-4-epoxyethylcyclohexane; 4-vinylcyclohexene diepoxide	203-437-7	106-87-6	Carc. 1B Muta. 2 Repr. 1B Acute Tox. 3 Acute Tox. 4	H350 H341 H360F H331 H302	GHS08 GHS06 Dgr	H350 H341 H360F H331 H302		inhalation: ATE = 0.5 mg/L (dusts or mists) oral: ATE = 1847 mg/kg bw	

15. Mecoprop-P (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 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	607-434-00-5	mecoprop-P [1] and its salts (R)-2-(4-chloro-2-methylphenoxy)propionic acid	240-539-0	16484-77-8	Acute Tox. 4* Eye Dam. 1 Aquatic Chronic 2	H302 H318 H411	GHS07 GHS05 GHS09 Dgr	H302 H318 H411			
Dossier submitters proposal	607-434-00-5	mecoprop-P (ISO) [1] and its salts; (R)-2-(4-chloro-2-methylphenoxy)propionic acid [1] and its salts	240-539-0 [1]	16484-77-8 [1]	**Modify** Acute Tox. 4 Aquatic Chronic 3	**Retain** H302 **Modify** H412	**Retain** GHS07 GHS05 Dgr **Remove** GHS09	**Retain** H302 **Modify** H412		**Add** oral: ATE = 431 mg/kg bw	
RAC opinion	607-434-00-5	mecoprop-P (ISO) [1] and its salts; (R)-2-(4-chloro-2-methylphenoxy)propionic acid [1] and its salts	240-539-0 [1]	16484-77-8 [1]	**Modify** Acute Tox. 4 Aquatic Chronic 1 **Add** Aquatic Acute 1	**Retain** H302 **Modify** H410 **Add** H400	**Retain** GHS07 GHS05 GHS09 Dgr	**Retain** H302 **Modify** H410		**Add** oral: ATE = 431 mg/kg bw M=10 M=10	
Resulting entry in Annex VI if adopted by Commission	607-434-00-5	mecoprop-P (ISO) [1] and its salts; (R)-2-(4-chloro-2-methylphenoxy)propionic acid [1] and its salts	240-539-0 [1]	16484-77-8 [1]	Acute Tox. 4 Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	H302 H318 H400 H410	GHS07 GHS05 GHS09 Dgr	H302 H318 H410		oral: ATE = 431 mg/kg bw M=10 M=10	

Table 2

1. 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	Human health to be added Aquatic Chronic 1	H410	GHS09 Wng	H410		M=1	
RAC opinion	TBD	trinexapac-ethyl (ISO); ethyl 4-[cyclopropyl(hydroxy)methylene]-3,5-dioxocyclohexanecarboxylate	-	95266-40-3	Human health to be added Aquatic Chronic 1	H410	GHS09 Wng	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	Aquatic Chronic 1	H410	GHS09 Wng	H410		M=1	

Part III. List of Attendees of the RAC-50 meeting

RAC Members
Agapiou Agapios
Aquilina Gabriele
Andreou Kostas
Barański Bogusław
Biró Anna
Bjørge Christine
Borg Daniel
Branisteanu Radu (co-opted member)
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
Mullooly Yvonne
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
Dungey Stephen
Ilie Mihaela
Smith Andrew
Zeljezic Davor

Members' advisers
Hyytinen Eija-Riitta (Riitta Leinonen)
Kuittinen Marko (Riitta Leinonen)
Pandard Pascal (Laure Geoffroy)_Microplastics
Partosch Falko (Ralf Stahlmann)_CLH adviser for Methyl salicylate
Vega Milagros (Joao Carvalho)_CLH adviser for Triticonazole
Commission
Sylvain Bintein (DG ENV)
Berger Bernhard (DG ENV)
Luvara Giuseppina (DG ENV)
Rozwadowski Jacek (DG GROW)
Tailler William (DG EMPL)
Regular stakeholder observers
Bernard Alice (ClientEarth)
Van de Broeck Steven (Cefic)
Comini Andrea (EuCheMS)
Romano Mozo Dolores (EEB)
Rowe Rocky (ECPA)
Verougstraete Violaine (Eurometaux)
Invited experts
Sendor Thomas (Ramboll)_AfA oPnEO
Susana Viegas (replacing RAC Member Joao Carvalho)

Dossier submitters
Correll Myhre Ingunn (NO)_PFHxS
Fotland Oystein Tor (NO)_PFHxS
Steward Alexandra (SE)_Skin sensitisers in textile
Occasional stakeholders
Cristina Arregui (IFRA)_methyl salicylate
Karolina Brzuska (CosmeticsEurope)_methyl salicylate
Buijs Nathalie (MedTech Europe)_microplastics, D4/D57D6, DMF_formaldehyde_cobalt salts_boric acid and borates
Doome Roger (IMA-Europe)_boric acid and borates
Drmac Dunja (Euratex)_formaldehyde_microplastics_skin sensitisers in textile
Fournier Paul (CIRFS)_DMF
Hayatifar Mohammad (EuPC)_calcium cyanamine_ cobalt salts_DMF_formaldehyde_microplastics_skin sensitisers in textile
Laroche Charles (IFRA)_microplastics
Scazzola Roberto (A.I.S.E)_microplastics
Simbor Perez Laia (ETRMA)_formaldehyde, microplastics, cobalt salts
Stakeholder experts
Al-Husainy Wasma (ECPA/Shell)_4-methylpentan-2-one
Ballach Jochen (Euratex/CIRFS)_microplastics/DMF
Bonifay Sebastien (ECPA/ECPA Members)_microplastics
Bowmann Werner (ECPA/Bayer)_desmedipham
Buschmann Jochen (Cosmetics Europe/General and Reproductive Toxicology)_methyl SA
Frericks Marcus (ECPA/BASF)_triconazole
Hartmann Kirstin (ECPA/Bayer)_trifloxystrobin

Jacobi Sylvia (Cefic/Sector Group Catalysts Europe)_cobalt salts
Leibold Edgar (Cefic/Formacare)_formaldehyde
Lloyd Sara (ECPA/Syngenta)_emamectin_trine-xapac
Meurer Krista (ECPA/BASF)_dimethomorph
Mihaylova Dilyana (EEB/Fauna&Flora)_microplastics
Mortier Nike (ClientEarth/OWS)_microplastics
Moxon Mary (ECPA/Nufarm)_mecoprop-p
Mulato Riccardo (A.I.S.E/YARA)_microplastics
Plotzke Kathy (Cefic/CES-Silicone Europe)_D4/D5/D6
Salthammer Tunga (EuPC/Fraunhofer WKI)_formaldehyde
Serrano Ramon Blanca (Cefic/Cefic)_microplastics
Tesh Sheila (ECPA/FMC)_clomazone
Viegas Vanessa (Eurometaux/Cobalt Institute and Cobalt REACH Consortium Ltd)_Cobalt salts
Warren Simon (ECPA/Exponent)_ethametsulfuron-methyl
Zeegers Maurice (CIRFS/CAPHRI)_DMF
Yamada Tomoya (ECPA/Sumitomo)_esfenvalerate
REMOTE PARTICIPANTS
RAC Members
Carvalho Joao
Husa Stine
Ilie Mihaela
Losert Annemarie
Printemps Nathalie

Members' advisers
Boel Els (Julie Seba)
Drost Wiebke (Michael Neumann)
Dussart Aurelie (Julie Seba)
Esposito Dania (Pietro Paris)
Kinzl Max (Annemarie Losert)
Meys Catherine (Julie Seba)
Moilanen Marianne (Riitta Leinonen)
Russo Maria Teresa (Gabriele Aquilina)
SEAC rapporteurs
Bergs Ivars (Cobalt salts)
Cogen Simon (microplastics, PFxS)
Kiiski Johanna (PFHxS)
Rouw Aarnout (OPE Boehringer and Ortho)
Thiele Karen (microplastics)
Dossier submitters
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FR
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IT
Catone Tiziana
NL
Cnubben Nicole
Geraets Lisbeth
Guichelaar Samantha
Van den Berg Suzanne
Van Herwijnen Rene
NO
Heggelund Audun
PL
Dominiak Dorota
SE
Johansson Olof (microplastics)
Mork Anna-Karin (Skin sensitizers in textile)
EFSA
Mangas Iris
Commission
Baricic Peter
Bertato Valentina
Gutierrez Miriam
Hualde-Grasa Eva Patricia
Jezso Veronika
Krassnig Christian
Lekatos Stylianos

ECHA staff in plenary
Berges Markus
Blainey Mark
Bowmer Tim, Chairman
Broeckaert Fabrice
Di Bastiano Augusto
Dvorakova Dana
Georgiadis Nikolaos
Gmeinder Michael
Hellsten Kati
Henrichson Sanna
Hollins Stephen
Jones Stella
Karjalainen Ari
Kivelä Kalle
Kokkola Leila
Lapenna Silvia
Lefevre-Brevart Sandrine
Ludborzs Arnis
Marques-Camacho Mercedes
Montiel Pablo
Nicot Thierry
Nygren Jonas
Orispää Katja
O´Rourke Regina
Peltola Jukka
Peltola-Thies Johanna
Perazzolo Chiara
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Prevedouros Konstantinos
Regil Pablo
Roggeman Maarten

Sadam Diana	
Simoes Ricardo	
Simpson Peter	
Smilovici Simona	
Sosnowski Piotr	
Sjuth Linda	
Stoyanova Evgenia	
Uphill Simon	
Vainio Matti	
Van Haelst Anniek	

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-50 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-50 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-49 meeting

ANNEX IV Administrative issues and information items

9 September 2019
RAC/A/50/2019

Final Agenda
50th meeting of the Committee for Risk Assessment

9 - 13 September 2019
and
16 – 20 September 2019

ECHA Conference Centre (Annankatu 18, Helsinki)

Monday 9 September starts at 14.00
Friday 13 September breaks at 13.00
Monday 16 September resumes at 14.00
Friday 20 September ends at 13.00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/50/2019
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, DNEL/dose-response relationships, Article 95(3) requests and Article 77(3)(c) requests

Item 5 – Report from other ECHA bodies and activities

a) Report on RAC 49 action points, written procedures and update on other ECHA bodies

RAC/50/2019/01
Room document
For information

b) RAC workplan for all processes

For information

c) Annual update of RAC accredited stakeholders' list

The Secretariat will update you on the requests from stakeholder observers to attend RAC meetings since the last review of the RAC stakeholder's. You will be invited to agree on the updated list of the accredited stakeholder organisations to RAC for this year.

RAC/50/2019/02
(restricted)
For agreement

Item 6 – Harmonised classification and labelling (CLH)

6.1 General CLH issues

a) CLP– suggested changes in the timing of the Appointment of rapporteurs

RAC/50/2019/03
For information

6.2 CLH dossiers

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

4-methylpentan-2-one: acute toxicity (all routes of exposure), serious eye damage / eye irritation, skin corrosion / irritation, skin sensitisation, STOT RE, STOT SE 3 (narcotic effects), germ cell mutagenicity, toxicity to reproduction, aspiration hazard, EUH066
trinexapac-ethyl (ISO): environmental hazards

clomazone (ISO): acute toxicity (all routes of exposure), serious eye damage /eye irritation, skin corrosion / irritation, skin or respiratory sensitisation, STOT RE, germ cell mutagenicity, carcinogenicity, aspiration hazard, environmental hazards

citric acid: physical hazards (explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, corrosive to metals), acute toxicity (all routes of exposure), serious eye damage / eye irritation, respiratory or skin sensitisation, germ cell mutagenicity, carcinogenicity, toxicity to reproduction, STOT RE, environmental hazards

desmedipham (ISO): environmental hazards

phenmedipham (ISO): environmental hazards

triticonazole: acute toxicity (dermal and inhalation routes of exposure), STOT SE, skin corrosion/irritation, serious eye damage/irritation, respiratory sensitisation and skin sensitisation, environmental hazards

trifloxystrobin (ISO): environmental hazards

esfenvalerate (ISO): acute toxicity (oral route of exposure), skin sensitisation, germ cell mutagenicity, environmental hazards

ethametsulfuron-methyl (ISO): acute toxicity (all routes of exposure), STOT SE, STOT RE, serious eye damage / eye irritation, skin corrosion /irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, environmental hazards, hazardous to the ozone layer

emamectin benzoate (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), acute toxicity (all routes of exposure),

serious eye damage / eye irritation, skin corrosion / irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, STOT RE (except SCLs), environmental hazards

B. Hazard classes for agreement with plenary debate

1) Methyl salicylate
2) 4-methylpentan-2-one
3) Clomazone (ISO)
4) Citric acid
5) Desmedipham
6) Phenmedipham (ISO)
7) Triticonazole
8) Boric acid [1]; Diboron trioxide [2]; Tetraboron disodium heptaoxide, hydrate [3]; Disodium tetraborate, anhydrous [4]; Orthoboric acid sodium salt [5]; Disodium tetraborate decahydrate [6]; Disodium tetraborate pentahydrate [7]
9) Trifloxystrobin (ISO)
10) Esfenvalerate (ISO)
11) ethametsulfuron-methyl (ISO)
12) dimethomorph (ISO)
13) Emamectin benzoate (ISO)
14) 1,2-epoxy-4-epoxyethylcyclohexane
15) mecoprop-P (ISO)

For discussion and adoption

Item 7 – Restrictions

7.1 Restriction Annex XV dossiers

a) Conformity check and key issues discussion

1) Calcium cyanamide in fertilisers

For agreement

b) Opinion development

1) Skin sensitisers in textile – first draft opinion
2) Perfluorohexane-1-sulphhonic acid, its salts and related substances – first draft opinion
3) Siloxanes (D4, D5 and D6) – second draft opinion
4) Formaldehyde and formaldehyde releasers – second draft opinion
5) Microplastics – second draft opinion

For discussion

6) *N*,*N*-dimethylformamide- final draft opinion
7) Cobalt salts – final draft opinion

For adoption

Item 8 – Authorisation

8.1 General authorisation issues

a) Update on incoming/future applications

b) OPnEO – consideration of approaches to risk assessment

For information/discussion

8.2 Authorisation applications

a) Discussion on key issues
   1. 27 applications for authorisation from May 2019 submission window (OPE/NPE, CTPht, Cr(VI))

For discussion

b) Agreement on draft opinions

1. CT_TES (1 use)
2. ~~SC_Ariston (1 use)~~ – removed from the agenda
3. ~~SD_Bussi (1 use)~~ – removed from the agenda
4. CTPht_Ariane (1 use)
5. OPE_Boehringer (1 use)
6. OPE_Ortho (2 uses)

For discussion and agreement

Item 9 – AOB

AfA, a horizontal issue entitled "Qualification of risks to the environment for 4-ter-OP"

RAC/50/2019/04
For discussion and agreement

Item 10 – Action points and main conclusions of RAC-50

Table with Conclusions and Action points from RAC-50

For adoption

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-50 – 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 9 September: 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 7 – Restrictions

Evening session

Tuesday 10 September: Morning session

Item 7 – Restrictions

Tuesday 10 September: Afternoon session

Item 7 – Restrictions

Item 8 – Authorisation applications

Wednesday 11 September: Morning session

Item 7 – Restrictions

Wednesday 11 September: Afternoon session

Item 7 – Restrictions

Evening session

Thursday 12 September: Morning session

Item 8 – Authorisation applications

Thursday 12 September: Afternoon session

Item 8 – Authorisation applications

Friday 13 September: Morning session

Item 8 – Authorisation applications

Item 5 – Annual update of RAC accredited stakeholders' list

Item 9 - AOB

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-50 – WEEK 2

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

Monday 16 September: Afternoon session

Item 1 – Welcome and Apologies

Item 3 – Declarations of conflicts of interest to the Agenda

Item 6 – CLH dossiers

Tuesday 17 September: Morning session

Item 6 – CLH dossiers

Tuesday 17 September: Afternoon session

Item 6 – CLH dossiers

Wednesday 18 September: Morning session

Item 6 – CLH dossiers

Wednesday 18 September: Afternoon session

Item 6 – CLH dossiers

Evening: Formal dinner

Thursday 19 September: Morning session

Item 6 – CLH dossiers

Thursday 19 September: Afternoon session

Item 6 – CLH dossiers

Friday 20 September: Morning session

Item 4 – Appointment of rapporteurs

Item 6 – General CLH issues

Item 6 – CLH dossiers

Item 9 – AOB

Item 10 – Action points and main conclusions of RAC-50

Annex II (RAC 50)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC 50 meeting.

Document number	Title
RAC/A/50/2019	Final Draft Agenda
RAC/A/50/2019 Restricted	Draft outline agenda
RAC/50/2019/01 Room document	Administrative issues and information items
RAC/50/2019/02 Restricted	Annual update of RAC accredited stakeholders´ list
RAC/50/2019/03	CLP-suggested changes in the timing of the Appointment of rapporteurs
RAC/50/2019/04 Room document	Authorisation applications –Agreement on draft opinions Qualification of risks to the environment for 4-ter-OP

ANNEX III (RAC-50)

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		
Restrictions		

New dossiers

Dossier / DS	RAC Member	Reason for potential CoI / Working for
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.
Applications for Authorisation		
-	-	-
Harmonised classification & labelling		
1) clomazone (ISO) **DK**	Peter Hammer SORENSEN	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
	Lea Stine TOBIASSEN	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) 1,2-epoxy-4-epoxyethylcyclohexane **2) Emamectin benzoate (ISO)** **3) dimethomorph (ISO)** **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) desmedipham (ISO) **2) phenmedipham (ISO)** **FI**	Riitta LEINONEN	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. Personal involvement in 1) and 2).
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.
Methyl salicylate **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.
Citric acid **BE**	Julie SEBA	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
1) 4-methylpentan-2-one **2) Triticonazole** **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
Boric acid and borates **SE**	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. No personal involvement
	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

Helsinki, 4 September 2019

RAC/50/2019/01

ROOM DOCUMENT

50TH MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

9 - 13 September 2019
and
16 - 20 September 2019

Helsinki, Finland

Concerns: **Administrative issues and information items**

Agenda Point: **5a**

Action requested: **for information**

ADMINISTRATIVE ISSUES AND INFORMATION ITEMS

1 Status report on the RAC-49 Action Points

The RAC-49 action points due for RAC-50 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-49	9 August 2019	closed

2.2 RAC consultations (status by 3 September 2019)

Subject / document	Deadline	Status / follow-up
Harmonised classification and labelling		
thiophanate-methyl (ISO) – consultation on the FINAL ADOPTED opinion	18 July 2019	closed
trinexapac-ethyl (ISO) / ENV hazards only	2 August 2019	closed
methyl salicylate	13 August 2019	closed
4-methylpentan-2-one; isobutyl methyl ketone	2 August 2019	closed
clomazone (ISO)		closed
citric acid	2 August 2019	closed
desmedipham (ISO)	13 August 2019	closed
phenmedipham (ISO)	13 August 2019	closed
triticonazole	12 August 2019	closed
Boric acid [1]; Diboron trioxide [2]; Tetraboron disodium heptaoxide, hydrate [3]; Disodium tetraborate, anhydrous [4]; Orthoboric acid sodium salt [5]; Disodium tetraborate decahydrate [6]; Disodium tetraborate pentahydrate [7]	13 August 2019	closed
trifloxystrobin (ISO)	13 August 2019	closed
esfenvalerate (ISO)	13 August 2019	closed
ethametsulfuron-methyl (ISO)	13 August 2019	closed
dimethomorph (ISO)	13 August 2019	closed
emamectin benzoate (ISO)	17 August 2019	closed

Subject / document	Deadline	Status / follow-up
1,2-epoxy-4-epoxyethylcyclohexane; 4-vinylcyclohexene diepoxide	13 August 2019	closed
mecoprop-P (ISO)	14 August 2019	closed
Application for Authorisation / Review Report		
CT_TES SC_Ariston SD_Bussi OPE_Boehringer OPE_Ortho OPE_Stago OPE_Sebia NPE_Sebia OPE_bioMerieux CTPht_Ariane OPE_BioMarin Consultations on applications for authorisation	3 July 2019	closed
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 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	2 October 2019	ongoing
Restrictions		
Consultations on the third draft opinion on DMF, on the second draft opinion on formaldehyde and	30 August 2019	closed

Subject / document	Deadline	Status / follow-up
formaldehyde releasers, on the second draft opinion on Microplastics		
Consultations on the second version of the draft opinion on D4/D5/D6, and on the fifth version of the draft opinion on Cobalt salts	4 September 2019	closed
Consultation on the conformity of Annex XV dossiers on calcium cyanimide	2 September 2019	closed

2.3 Calls for expression of interest

Calls for expression of interest	Date	Outcome
Harmonised classification and labelling		
none		
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[3].		
Restriction n/a		

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

Appointment of (Co-)rapporteur(s)	Substance	Deadline	Outcome
Harmonised classification and labelling - no written procedures			
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 SEAC

Opinion(s)	Sent on
Opinions sent to the European Commission, the Member States and applicants	
RR1_TCE_Spolana (1 opinion)	11 June 2019

[3] 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)