RAC/M/52B-1/2020

Final

8 May 2020

Minutes of the 52nd Meeting

of the Committee for Risk Assessment

RAC 52B (CLH week)

Rescheduled in two parts from March 16-20 due to Corona virus restrictions

Part 1

Monday, 4 May 2020 (09.00 to 18.30)

Remote meeting

Summary Record of the Proceedings, and Conclusions and action points

Agenda point	
1. Chairman's address The Chairman Tim Bowmer welcomed the participants to this remote meeting of the Committee for Risk Assessment, hosted from the ECHA Conference Centre in Helsinki. He noted that although ECHA staff had been teleworking since 17 March and this will continue at least until 25 May, the agency is fully functional and all meetings are going ahead as planned. He noted that the Committee Rules of Procedure apply un-amended and that this first short plenary of the RAC to be held remotely provides an opportunity to explore consensus building without physical presence. It will help to prepare for the upcoming RAC 53 June plenaries and for RAC 52B Part 2 which will be held remotely (the latter provisionally from 5 to 9 October). In preparation for this meeting, a technical rehearsal was held on 27 April to familiarise participants with the IT software in use. Nevertheless, the Chairman again introduced the participants to the workings of the particular IT software used to host the meeting and the Committee members to the system of polling to record the quorum present at intervals during the meeting.	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/52B-1/2020**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-52B Part 1 minutes.
4. Harmonised classification and labelling (CLH)	
4.1 CLH dossiers	
A. Substances with hazard classes for agreement by A-listing following the usual scrutiny but without plenary debate • Acetamiprid (ISO): acute toxicity (oral) • Cyfluthrin (ISO): physical hazards, acute toxicity (dermal), skin corrosion / irritation, serious eye damage / eye irritation • Beta-cyfluthrin (ISO): physical hazards, acute toxicity (dermal), skin corrosion / irritation, serious eye damage / eye irritation	

B. Substances with hazard classes for agreement in plenary session

1. acetamiprid (ISO)
2. cyfluthrin (ISO)
3. beta-cyfluthrin (ISO)
4. silanamine

1. acetamiprid (ISO)

The Chairman welcomed the expert accompanying the ECPA Regular Stakeholder Observer and reminded the Committee that acetamiprid (ISO) is an active substance in plant protection products used as an insecticide to control herbivorous (sucking and biting) insects and is applied as a foliar spray on crops. It has an existing entry in Annex VI to the CLP Regulation as Acute Tox. 4*; H302 (minimum classification) and Aquatic Chronic 3; H412. Legal deadline for the adoption of an opinion is 23 April 2020.

The DS (NL) proposed to modify/add the following human health hazards: Acute Tox. 3; H301, Carc. 2; H351 and Repr. 2; H361d.

Acute oral toxicity, carcinogenicity, toxicity to reproduction and hazards to the aquatic environment were open for comments during the public consultation.

At RAC-51, the Committee agreed to classify acetamiprid (ISO) for hazards to the aquatic environment (Aquatic Acute 1; H400, M=10 and Aquatic Chronic 1; H410, M=10) in line with the DS proposal.

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): 140 mg/kg bw, Repr. 2; H361d]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

The expert accompanying the ECPA Regular Stakeholder Observer commented on developmental delay and on developmental toxicity.

2. cyfluthrin (ISO)

The Chairman welcomed the expert accompanying the ECPA Regular Stakeholder Observer and reported that cyfluthrin (ISO) is an active substance used in biocidal products as an insecticide (pyrethroid insecticides). It has an existing entry in Annex VI to the CLP Regulation for Acute Tox. 2*; H300, Acute Tox. 3*; H331 (minimum classifications), Aquatic Acute 1; H400, Aquatic Chronic 1; H410, M = 1000. Legal deadline for the adoption of an opinion is 29 May 2020.

The DS (DE) proposed to add STOT SE 3; H335 and Lact.; H362 and to modify/confirm: acute oral and inhalation toxicity (Acute Tox. 2; H300, ATE (oral): 14.3 mg/kg bw, Acute

Tox. 2; H330, ATE (inhalation): 0.081 mg/L (dusts or mists)) and for hazards to the aquatic environment (Aquatic Acute 1; H400, M = 1 000 000 and Aquatic Chronic 1; H410, M = 100 000). Physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT SE, STOT RE, reproductive toxicity and hazards to the aquatic environment were open for comments during the consultation.	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [STOT SE 1; H370 (nervous system), Lact.; H362, Acute Tox. 2; H300, ATE (oral): 14 mg/kg bw, Acute Tox. 2; H330, ATE (inhalation): 0.14 mg/l (dusts or mists), Aquatic Acute 1; H400, M=1 000 000, Aquatic Chronic 1; H410, M=1 000 000]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
The expert accompanying the ECPA Regular Stakeholder Observer commented on acute oral toxicity, on neurotoxicity, on development and on lactation.	
3. beta-cyfluthrin (ISO)	
The Chairman welcomed the expert accompanying the ECPA Regular Stakeholder Observer and reported that beta-cyfluthrin (ISO) is an active substance used in plant protection products. It has an existing entry in Annex VI to the CLP Regulation for Acute Tox. 2*; H300, Acute Tox. 2*; H330 (minimum classifications), Aquatic Acute 1; H400, Aquatic Chronic 1; H410, M = 1000. Legal deadline for the adoption of an opinion is 29 May 2020. The DS (DE) proposed to add STOT SE 3; H335 and Lact.; H362 and to modify/confirm: acute oral and inhalation toxicity (Acute Tox. 2; H300, ATE (oral): 14.3 mg/kg bw, Acute Tox. 2; H330, ATE (inhalation): 0.081 mg/L (dusts or mists)) and for hazards to the aquatic environment (Aquatic Acute 1; H400, M = 1 000 000 and Aquatic Chronic 1; H410, M = 100 000). Physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT SE, STOT RE, reproductive toxicity and hazards to the aquatic environment were open for comments during the consultation.	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [STOT SE 1; H370 (nervous system), Lact.; H362, Acute Tox. 2; H300, ATE (oral): 11 mg/kg bw, Acute Tox. 2; H330, ATE (inhalation): 0.081 mg/l (dusts or mists), Aquatic Acute 1; H400, M=1 000 000, Aquatic Chronic 1; H410, M=1 000 000]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

The expert accompanying the ECPA Regular Stakeholder Observer commented on acute oral toxicity, on neurotoxicity, on development and on lactation. One intervention that was missed due to technical issues was later repeated at the request of the Chairman.

4. silanamine

The Chairman welcomed the experts accompanying the CEFIC and the Eurometaux Regular Stakeholder Observers and reminded that RAC had adopted its opinion on the Silanamine dossier at RAC-51 in December 2019 (by simple majority) with a proposal for the harmonised classification and labelling as Acute Tox. 2; H330, with ATE(inhalation) = 0.45 mg/L. RAC also agreed that the Secretariat would launch an *ad hoc* targeted consultation on the data not included in the original CLH report but available in the scientific literature that led to the conclusion on the classification on acute toxicity by inhalation. This *ad hoc* consultation was conducted from 3 February to 17 February 2020, during which a number of comments were received from Industry. Apart from the scientific issues raised in the comments, a recurring comment was that the Industry had not been aware that the substance was on the agenda for the December 2019 meeting.

In order to adequately reflect the comments received on the opinion (which had not yet been sent to the Commission) and in the interest of ensuring procedural fairness, the secretariat had re-opened the discussion on the acute toxicity classification and had scheduled the dossier for further discussion for 4 May 2020 RAC WebEx plenary.

RAC took note of the outcome of the *ad hoc* consultation. RAC reviewed the data on the studies and addressed industries comments in detail but did not change its earlier classification conclusion as a result.	**Rapporteurs** to finalise the opinion with the outcome of the *ad hoc* consultation and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

The experts accompanying the CEFIC and the Eurometaux Regular Stakeholder Observers commented on acute inhalation toxicity as well as on the procedural aspects. The COM observer also commented on procedural aspects.

5. AOB

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6. Action points and main conclusions of RAC-52B-1

SECR to upload the adopted action points to CIRCA BC.

Table 1: CLH opinions which were adopted at RAC-52B-1

1. **acetamiprid (ISO)**
2. **cyfluthrin (ISO)**
3. **beta-cytluthrin (ISO)**
4. **silanamine**

Table 1

1. Acetamiprid (ISO)

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	608-032-00-2	acetamiprid (ISO); (1E)-N-[(6-chloropyridin-3-yl)methyl]-N'-cyano-N-methylethanimidamide; (E)-N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine	-	135410-20-7	Acute Tox. 4* Aquatic Chronic 3	H302 H412	GHS07 Wng	H302 H412			
Dossier submitters proposal	608-032-00-2	acetamiprid (ISO); (1E)-N-[(6-chloropyridin-3-yl)methyl]-N'-cyano-N-methylethanimidamide; (E)-N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine	-	135410-20-7 160430-64-8	**Modify** Aquatic Chronic 1 Acute Tox. 3 **Add** Carc. 2 Repr. 2 Aquatic Acute 1	**Retain** H410 **Modify** H301 **Add** H351 H361d H400	**Remove** GHS07 Wng **Add** GHS06 GHS08 GHS09 Dgr	**Retain** H410 **Modify** H301 **Add** H351 H361d		**Add** M = 10 M = 100	
RAC opinion	608-032-00-2	acetamiprid (ISO); (1E)-N-[(6-chloropyridin-3-yl)methyl]-N'-cyano-N-methylethanimidamide; (E)-N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine	-	135410-20-7 160430-64-8	**Modify** Aquatic Chronic 1 Acute Tox. 3 **Add** Repr. 2 Aquatic Acute 1	**Retain** H410 **Modify** H301 **Add** H361d H400	**Remove** GHS07 Wng **Add** GHS06 GHS08 GHS09 Dgr	**Retain** H410 **Modify** H301 **Add** H361d		**Add** oral: ATE = 140 mg/kg bw M = 10 M = 10	
Resulting Annex VI entry if agreed by COM	608-032-00-2	acetamiprid (ISO); (1E)-N-[(6-chloropyridin-3-yl)methyl]-N'-cyano-N-methylethanimidamid	-	135410-20-7 160430-64-8	Repr. 2 Acute Tox. 3 Aquatic Chronic 1 Aquatic Acute 1	H361d H301 H410 H400	GHS08 GHS06 GHS09 Dgr	H361d H301 H410		oral: ATE = 140 mg/kg bw M = 10 M = 10	

		e; (E)-N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine									

2. Cyfluthrin (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	607-253-00-1	cyfluthrin (ISO); α-cyano-4-fluoro-3-phenoxybenzyl-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate	269-855-7	68359-37-5	Acute Tox. 3* Acute Tox. 2* Aquatic Acute 1 Aquatic Chronic 1	H331 H300 H400 H410	GHS06 GHS09 Dgr	H331 H300 H410		M = 1000	
Dossier submitters proposal	607-253-00-1	cyfluthrin (ISO); α-cyano-4-fluoro-3-phenoxybenzyl-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate	269-855-7	68359-37-5	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Lact. STOT SE 3 **Modify** Acute Tox. 2 Acute Tox. 2	**Retain** H300 H400 H410 **Add** H362 H335 **Modify** H330	**Retain** GHS06 GHS09 Dgr	**Retain** H300 H410 **Add** H362 H335 **Modify** H330		**Add** inhalation: ATE = 0.081 mg/L (dusts or mists) oral: ATE = 14.3 mg/kg bw M = 100000 (chronic) **Modify** M = 1000000 (acute)	
RAC opinion	607-253-00-1	cyfluthrin (ISO); α-cyano-4-fluoro-3-phenoxybenzyl-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate	269-855-7	68359-37-5	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Lact. STOT SE 1 **Modify** Acute Tox. 2 Acute Tox. 2	**Retain** H300 H400 H410 **Add** H362 H370 (nervous system) **Modify** H330	**Retain** GHS06 GHS09 Dgr **Add** GHS08	**Retain** H300 H410 **Add** H362 H370 (nervous system) **Modify** H330		**Add** inhalation: ATE = 0.14 mg/L (dusts or mists) oral: ATE = 14 mg/kg bw M = 1000000 (chronic) **Modify** M = 1000000 (acute)	

Resulting Annex VI entry if agreed by COM	607-253-00-1	cyfluthrin (ISO); α-cyano-4-fluoro-3-phenoxybenzyl-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate	269-855-7	68359-37-5	Lact. Acute Tox. 2 Acute Tox. 2 STOT SE 1 Aquatic Acute 1 Aquatic Chronic 1	H362 H330 H300 H370 (nervous system) H400 H410	GHS06 GHS08 GHS09 Dgr	H362 H330 H300 H370 (nervous system) H410		inhalation: ATE = 0.14 mg/L (dusts or mists) oral: ATE = 14 mg/kg bw M = 1000000 M = 1000000	

3. Beta-cyfluthrin (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	607-254-00-7	α-cyano-4-fluoro-3-phenoxybenzyl-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate; beta-cyfluthrin	269-855-7	68359-37-5	Acute Tox. 2* Acute Tox. 2* Aquatic Acute 1 Aquatic Chronic 1	H330 H300 H400 H410	GHS06 GHS09 Dgr	H330 H300 H410			
Dossier submitters proposal	607-254-00-7	beta-cyfluthrin (ISO); reaction mass of *rel*-(R)-cyano(4-fluoro-3-phenoxyphenyl)methyl (1S,3S)-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate and *rel*-(R)-cyano(4-fluoro-3-phenoxyphenyl)methyl (1S,3R)-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	-	1820573-27-0	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Lact. STOT SE 3 **Modify** Acute Tox. 2 Acute Tox. 2	**Retain** H330 H300 H400 H410 **Add** H362 H335	**Retain** GHS06 GHS09 Dgr	**Retain** H330 H300 H410 **Add** H362 H335		**Add** inhalation: ATE = 0.081 mg/L (dusts or mists) oral: ATE = 14.3 mg/kg bw M = 1000000 M = 100000	
RAC opinion	607-254-00-7	beta-cyfluthrin (ISO); reaction mass of *rel*-(R)-cyano(4-fluoro-3-phenoxyphenyl)methyl (1S,3S)-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate and *rel*-(R)-cyano(4-fluoro-3-phenoxyphenyl)methyl (1S,3R)-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	-	1820573-27-0	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Lact. STOT SE 1 **Modify** Acute Tox. 2 Acute Tox. 2	**Retain** H330 H300 H400 H410 **Add** H362 H370 (nervous system)	**Retain** GHS06 GHS09 Dgr **Add** GHS08	**Retain** H330 H300 H410 **Add** H362 H370 (nervous system)		**Add** inhalation: ATE = 0.081 mg/L (dusts or mists) oral: ATE = 11 mg/kg bw M = 1000000 M = 1000000	
Resulting Annex VI entry if agreed by COM	607-254-00-7	beta-cyfluthrin (ISO); reaction mass of *rel*-(R)-cyano(4-fluoro-3-phenoxyphenyl)methyl (1S,3S)-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate and *rel*-(R)-cyano(4-fluoro-3-	-	1820573-27-0	Lact. Acute Tox. 2 Acute Tox. 2 STOT SE 1 Aquatic Acute 1 Aquatic Chronic 1	H362 H330 H300 H370 (nervous system) H400 H410	GHS06 GHS08 GHS09 Dgr	H362 H330 H300 H370 (nervous system) H410		inhalation: ATE = 0.081 mg/L (dusts or mists) oral: ATE = 11 mg/kg bw M = 1000000 M = 1000000	

		phenoxyphenyl)methyl (1S,3R)-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate									

4. Silanamine

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No Current Annex VI Entry										
Dossier submitters proposal	TBD	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide	272-697-1	68909-20-6	STOT RE 2	H373 (lungs, inhalation)	GHS08 Wng	H373 (lungs, inhalation)	EUH 066		
RAC opinion	TBD	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide	272-697-1	68909-20-6	Acute Tox. 2 STOT RE 2	H330 H373 (lungs, inhalation)	GHS06 GHS08 Dgr	H330 H373 (lungs, inhalation)	EUH066	ATE = 0.45 mg/L (dusts or mists)	
Resulting Annex VI entry if agreed by COM	TBD	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide	272-697-1	68909-20-6	Acute Tox. 2 STOT RE 2	H330 H373 (lungs, inhalation)	GHS06 GHS08 Dgr	H330 H373 (lungs, inhalation)	EUH066	ATE = 0.45 mg/L (dusts or mists)	

Part I. List of Attendees of the RAC-52B-part 1 Remote meeting

RAC Members
Aquilina Gabriele
Andreou Kostas
Barański Bogusław
Biró Anna
Bjørge Christine
Borg Daniel
Brovkina Julija
Carvalho João
de la Flor Tejero Ignacio
Dobrev Ivan
Docea Anca
Geoffroy Laure
Hakkert Betty
Husa Stine
Kapelari Sonja
Karadjova Irina
Leinonen Riitta
Losert Annemarie
Lund Bert-Ove
Martínek Michal
Menard Srpčič Anja
Moeller Ruth
Moldov Raili
Murray Brendan
Neumann Michael
Paris Pietro
Pribu Mihaela
Printemps Nathalie
Pęczkowska Beata
Rucki Marian
Santonen Tiina
Schlüter Urs
Schuur Gerlienke
Schulte Agnes
Sørensen Hammer Peter
Sogorb Miguel A.
Spetseris Nikolaos
Stahlmann Ralf
Tobiassen Lea Stine
Tsitsimpikou Christina
Užomeckas Žilvinas
Varnai Veda
Apologies, Members
Chankova-Petrova Stephka
Kadiķis Normunds
Séba Julie
Zeljezic Davor
Members' advisers
Boel Els (Julie Seba)
Hoffmann Frauke (Agnes Schulte)
Martin Theresa (Ralf Stahlmann)
Russo Maria Teresa (Gabriele Aquilina)
Sonnenburg Anna (Ralf Stahlmann)
Suutari Tiina (Riitta Leinonen)
Invited experts
Rodriguez Wendy (replacing RAC member Julie Seba)

Commission
Kiriazis Aléxandros
Kilian Karin
Dossier submitters
Groothuis Floris (NL) _Acetamiprid
Gall Andrea (DE)_Cyfluthrin; Beta-cyfluthrin
Herrmann Kristin (DE)_Cyfluthrin; Beta-cyfluthrin
Schulte Petra (DE)_Cyfluthrin; Beta-cyfluthrin
Regular stakeholder observers
Comini Andrea (EuCheMS)
Ruelens Paul (ECPA)
Van de Broeck Steven (Cefic)
Verougstraete Violaine (Eurometaux)
Stakeholder experts
Jacobi Silvia (Eurometaux/ Representing Albemarle as member of the SAS REACH consortium)_Silanamine
Krueger Nils (CEFIC/ASASP)_Silanamine
Richmond Emily (ECPA/ Exponent International (Nissan))_Acetamiprid
Watson Sheila (ECPA/Bayer)_ Cyfluthrin; Beta-cyfluthrin

ECHA staff in plenary
Blainey Mark
Bowmer Tim (Chairman)
Jones Stella
Karjalainen Ari
Kokkola Leila
Montiel Pablo
Myohanen Kirsi
Nygren Jonas
O'Rourke Regina
Peltola-Thies Johanna
Perazzolo Chiara
Sadam Diana
Simoes Ricardo
Smilovici Simona
Sosnowski Piotr
Spjuth Linda
Uphill Simon

Part II. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-52B-1 meeting

ANNEX II Declarations of conflicts of interest to the Agenda of the RAC-52B-1 meeting

ANNEX I (RAC-52B-1)

Final Agenda
52nd meeting of the Committee for Risk Assessment
CLH plenary - Part 1 (RAC 52B-1)

Monday, 4 May 2020
09.00-18.30 hrs

Remote meeting

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/52B-1/2020
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Harmonised classification and labelling (CLH)

4.1 CLH dossiers

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

- acetamiprid (ISO): acute toxicity (oral)
- cyfluthrin (ISO): physical hazards, acute toxicity (dermal), skin corrosion / irritation, serious eye damage / eye irritation
- beta-cyfluthrin (ISO): physical hazards, acute toxicity (dermal), skin corrosion / irritation, serious eye damage / eye irritation

B. Hazard classes for agreement with plenary debate

1) acetamiprid (ISO)
2) cyfluthrin (ISO)
3) beta-cyfluthrin (ISO)

4) silanamine

RAC had adopted its opinion on the Silanamine dossier at RAC-51 in December 2019 (by simple majority) with a proposal for the harmonised classification and labelling as Acute Tox. 2; H330, with ATE(inhalation) = 0,45 mg/L. RAC also agreed that the Secretariat would launch a targeted consultation on the data not included in the CLH report that led to the conclusion on the classification on acute toxicity by inhalation. This ad hoc consultation was conducted from 3 February to 17 February 2020, during which a number of comments were received from Industry. Apart from the scientific issues raised in the comments, a recurring comment was that the Industry were not aware that the substance was on the agenda for the December 2019 meeting.
In order to adequately reflect the comments received in the opinion and in the interest of ensuring procedural fairness, ECHA has therefore decided to re-open the discussion on the acute toxicity classification and has scheduled this discussion for the RAC WebEx on 4 May.

For discussion and adoption

Item 5 – AOB

Item 6 – Minutes of RAC-52B-1

Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-52B Part 1

For adoption

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-52

CLH plenary – *Part 1*

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

Monday 4 May 2020: Morning session

Item 1 – Welcome and Apologies
Item 2 – Adoption of the Agenda
Item 3 – Declarations of conflicts of interest to the Agenda
Item 4 – CLH dossiers

Monday 4 May 2020: Afternoon session

Item 8 – CLH dossiers
Item 6 – Minutes of RAC-52 CLH plenary *Part 1*

ANNEX II (RAC-52B-1)

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)		
Harmonised classification & labelling		
acetamiprid (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.
silanamine **FR**	Nathalie PRINTEMPS	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Tiina Santonen	Personal involvement in amorphous silicon dioxide compounds during her previous work (before joining RAC).

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
Harmonised classification & labelling		
1) Cyfluthrin (ISO) **2) Beta-cyfluthrin (ISO)** **DE**	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Urs SCHLUTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
		measures applied. No personal involvement.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Ivan DOBREV	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.