Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Complementary and OTC Medicines Regulatory & Technical Forum (ComTech)

Record of outcomes

Meeting 3rd May 2023

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TGA Participants _____ 3

s22 [redacted]

4.3 TGA Presentation: Sunscreen issues including TGA adoption of Sunscreen Standard AS/NZS and Toxicology review of sunscreen ingredients _____ 7

s22 [redacted]

External Participants

Participant	Organisation	Item
s47F [redacted]	ATGC	
	Accord	
	Accord	
	CHP Australia	
	CMA	Item 4.2
	CMA	

TGA Participants

Name	Position	Item
Cheryl McRae (Chair)	Assistant Secretary, Complementary and OTC Medicines Branch (COMB)	Item 2 Item 3
s22 [redacted]	Director, Complementary Medicines Evaluation Section (CMES)	Item 4.1
	Director, OTC Medicines Evaluation Section (COMB)	
	A/g Director, Business Improvement and Support Section (BISS)	Item 4.3 Item 4.6
	A/g Director, Listing Compliance Section (LCS)	
	Assistant Director, Listing Compliance Section (LCS)	Item 4.4
		Item 4.5
		Item 4.7
	Secretariat, BISS	

Apologies

Participant	Organisation
s47F [redacted]	ATGC, s47F [redacted]
	CHP Australia

s22

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s22

[redacted]

4.3 TGA Presentation: Sunscreen issues including TGA adoption of Sunscreen Standard AS/NZS and Toxicology review of sunscreen

s22

[redacted]

s22

The TGA provided an update on the US FDA 's proposal to remove certain ingredients from the Generally Recognised As Safe and Effective (GRASE) list. To date, there has been no further update from the US FDA. The TGA is conducting its own internal review of the safety of certain sunscreen ingredients, but at this stage, does not have a timeframe of when the review will be finalised. A TGA exposure model is being refined internally which will be utilised in determining the outcomes of the safety review.

In relation to benzophenone impurities in sunscreens, the TGA advised that they continue to test sunscreens in the market for this impurity and will take action if they find that levels are too high.

The TGA is also undertaking a review of the ARGS to reflect the changes in mandatory application requirements for listed medicines and therapeutic sunscreens.

Once the outcome of the sunscreen consultation is realised, further updates to the ARGS will occur as required and will be discussed at future ComTech meetings.

Finally, the TGA advised that future work is planned to review the Excluded Goods Order.

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Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Complementary and OTC Medicines Regulatory & Technical Forum (ComTech)

Record of outcomes

Meeting 18th October 2023

Contents

External Participants _____ 3

TGA Participants _____ 3

s22 [redacted]

4.3 TGA Verbal: Update on Sunscreens issues _____ 7

s22 [redacted]

External Participants

Participant	Organisation	Item
s47F [redacted]	New Zealand Ministry of Health (NZ MoH)	
	NZ MoH	
	NZ MoH	
	Association of Therapeutic Goods Consultants (ATGC)	
	ATGC	
	Accord	
	Accord	
	Accord	Observer
	Complementary Healthcare Products (CHP) Australia	
	CHP Australia	
	Complementary Medicines Australia (CMA)	
	CMA	Observer

TGA Participants

Name	Position	Item
Gaelene Pyke (Chair)	A/g Assistant Secretary (AS), Complementary and OTC Medicines Branch (COMB)	Item 2 Item 3
s22 [redacted]	Senior Scientific Evaluator, CMES	
	A/g Director, Complementary Medicines Evaluation Section (CMES)	Item 4.3
	A/g Director, Business Improvement and Support Section (BISS)	Item 4.3 Item 4.9
	Director, Listing Compliance Section (LCS)	Item 4.4
	Senior Scientific Evaluator, CMES	Item 4.8
	A/g Senior Scientific Evaluator, CMES	Item 4.5
	AS, HPRG Transformation Branch	Item 4.5
	A/g Director, Scientific Operations Management Section	Item 4.6
	Secretariat, BISS	

Apologies

Participant	Organisation
s47F [redacted]	CMA
s22 [redacted]	TGA

s22

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[redacted]

4.3 TGA Verbal: Update on Sunscreens issues

s22

[redacted]

Update on Benzophenone safe limit in sunscreens

The TGA provided an update on the Low-negligible risk consultation issue surrounding setting a safe limit for benzophenone in sunscreens – closed 14 September – noting that the consultation responses are currently being reviewed and thanked industry for the scientific information that has been received.

The TGA outlined that the consensus of the responses is that there does need to be a safe level set for benzophenone, however the limit proposed (26 ppm) in the consultation was quite restrictive and further work will need to be done in that space. The TGA noted that there is no rush to set a safety limit and the aim is to keep sunscreens within the low-risk category.

The TGA noted that scientific information relating to dermal absorption of benzophenone is being considered for establishing a more appropriate dermal absorption factor. With regards to an appropriate daily sunscreen exposure rate, however, the TGA noted that the only recommendation for a daily exposure rate currently available is that provided by the Cancer Council and acknowledged that it can be considered to be an overestimation when applying that to daily use for prolonged periods (i.e., 365 days of the year). On the other hand, the Scientific Committee on Consumer Safety (SCCS) prescribes a very different amount of 18g/day. It is important to note that this amount is not a recommendation by the SCCS but is based on habits and practice type data which is very different to recommendations from government and public health organisations in Australia as well as directions for use on Australian products. Moreover, the locations and jurisdictions where that data has been gathered from may not be relevant to Australia so further investigation into a more fit for purpose exposure model for the Australian context is required.

The TGA invited members to send examples of any exposure models that they may be aware of which could be useful. The TGA also informed that there is an exposure model being developed by TGA toxicology section and this would be consulted on for adoption with ComTech either at the next meeting or out-of-cycle.

Industry members noted that it is a good outcome from the consultative process and sought clarification as to whether any insight will be provided before the publication of the decisions of the consultation, and when consultation on the exposure model will occur.

The TGA confirmed that discussions will be had with industry members before a legislated safe limit of benzophenone is established, however noted that the outcome of the Low-Neg risk consultation may need to be deferred as a safe limit cannot be set in the absence of an appropriate daily exposure rate. In terms of the exposure model, the TGA noted that they could add this as an agenda item to the next ComTech meeting in May next year, or alternatively, could hold an out of session discussion first and allow industry to consult with their members, then if the exposure model is at an advanced enough point, the discussion at the next Comtech meeting could be more thorough.

ACTION items:

- Industry to email examples of exposure modelling through to the Comtech.secretariat@health.gov.au inbox
- TGA to consider options to consult on the exposure model currently being developed by the TGA toxicology section.

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Meeting Outcome Note

Sunscreen Working Group - Sunscreen excipient assessment fees

Date: 12 February 2025

Time: 9.30 am to 11 am

Location: TGA Fairbairn

External Participants

Participant	Organisation
s47F	Accord
	Accord
	Accord
	Accord
	Consumer Healthcare Products Australia
	Consumer Healthcare Products Australia
	Consumer Healthcare Products Australia

TGA Participants

Name	Position
Nick Henderson	First Assistant Secretary, Medicines Regulation Division
Avinash Clarke	Assistant Secretary, Complementary & Over the Counter medicines Branch
s22	Acting Director, Complementary Medicines Evaluation Section
	Director, Business Improvement and Support Section
	Assistant Director, Complementary Medicines Evaluation Section
	Regulatory Legal Services Branch
	Regulatory Legal Services Branch

Discussion items

s22

- Planning required for potential outcomes of scheduling consideration of active sunscreen ingredients and the downstream effects on sunscreen supply.

Meeting Outcome

s22 [redacted]

d. Discussion and planning for potential scheduling decisions on ingredients

(i) Prior discussion on any proposed changes
(ii) Consideration given to regulatory impacts
(iii) Implementation planning
(iv) Transition allowance

Action items

Industry to provide:

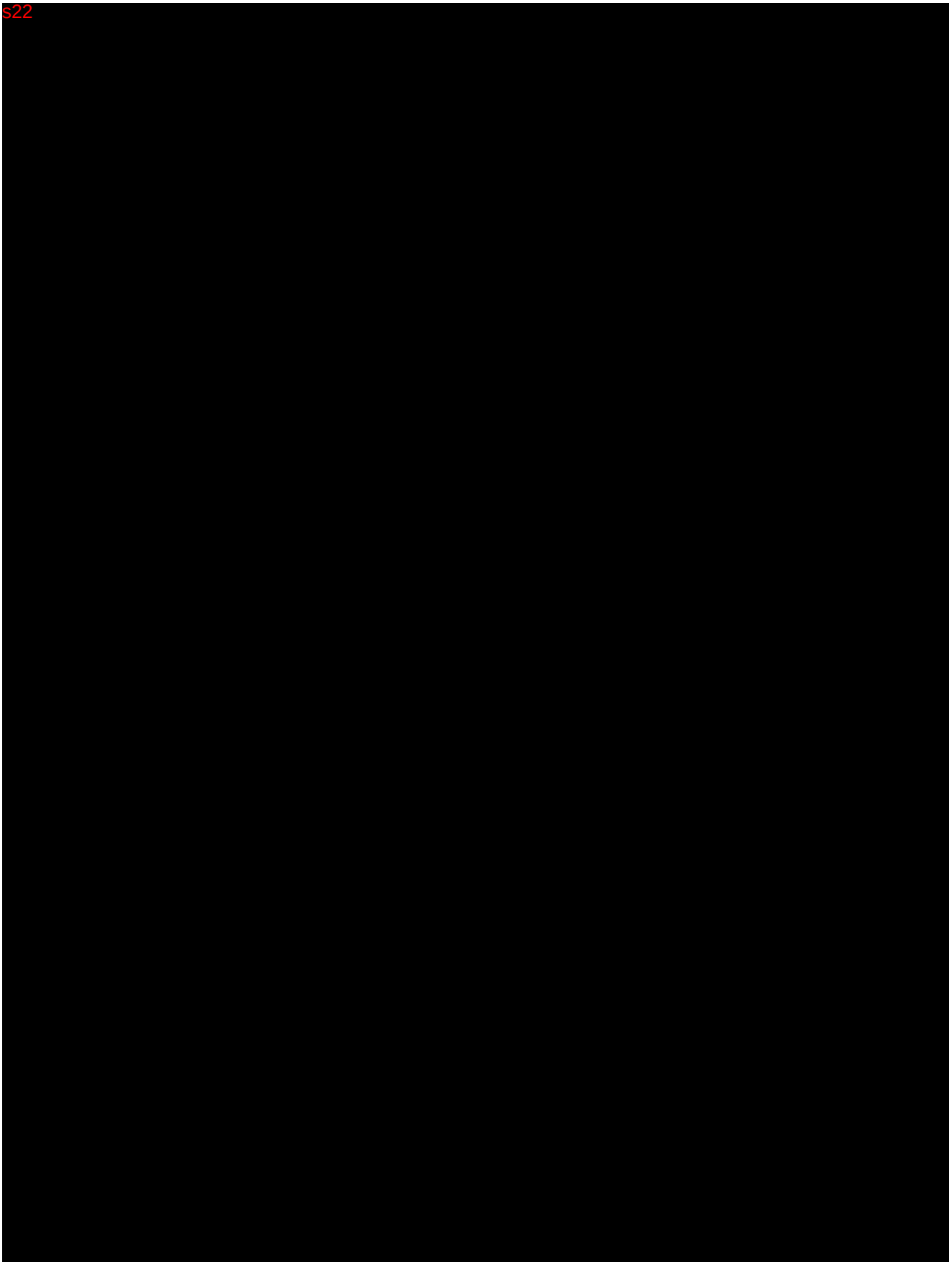
- s22 [redacted]
- Sunscreen market data
- s22 [redacted]

TGA to:

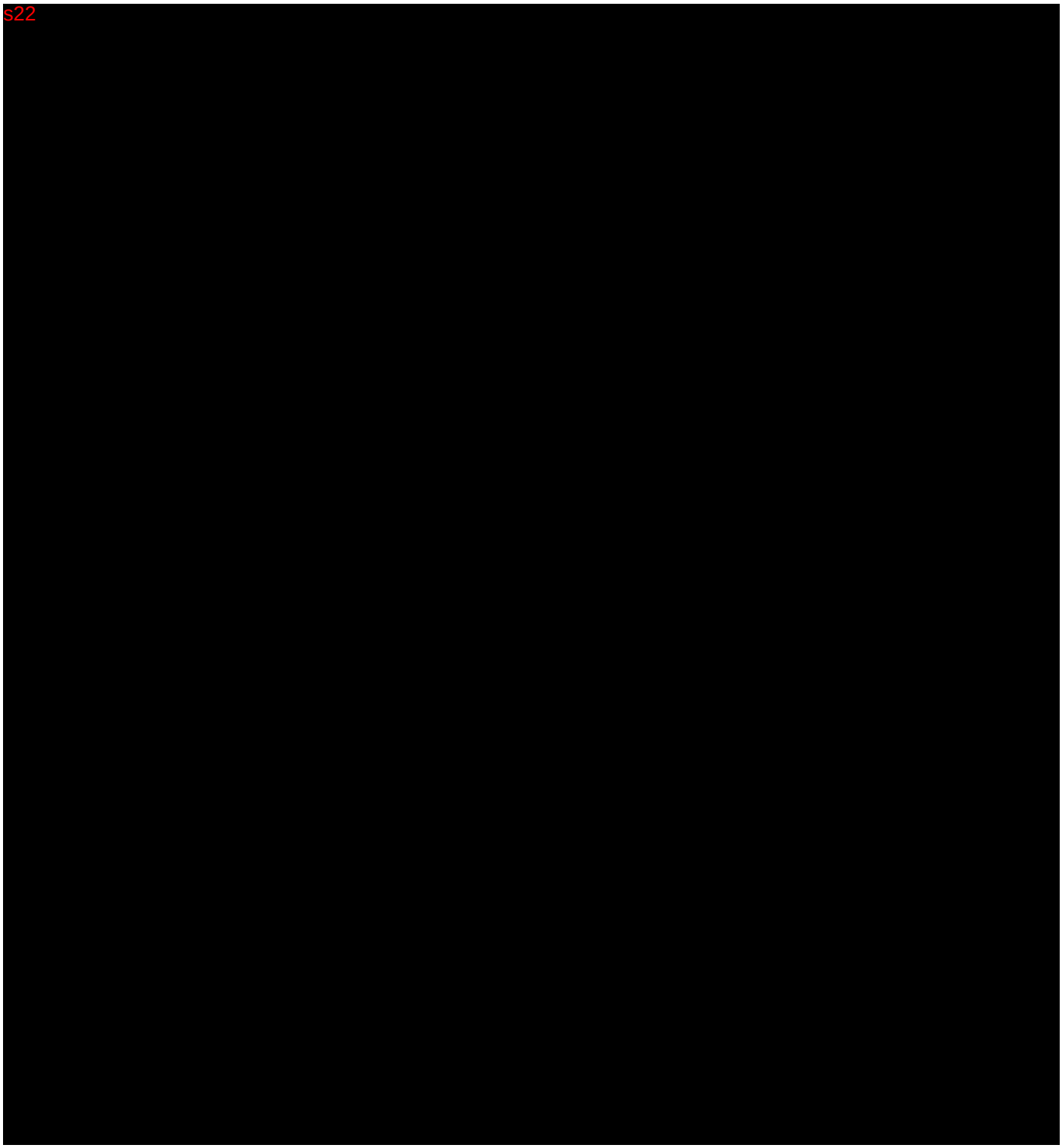
s22 [redacted]

- Provide plan for future activities related to sunscreens.
- Consider implementation planning and discussions with industry on scheduling changes.

s22



s22



Ingredient potential scheduling

CHPA

- There may be a struggle to supply sunscreens during scheduling process
- Will need to discuss and plan
- You know a change is coming, but you can't start acting until you know what the new rules are

Accord

- Concerned scheduling process doesn't consider the costs
- Reformulation and transition needs to be considered

TGA

- Scheduling committee welcome information on reformulation, costings etc
- Minister well briefed

From: s47F
To: s22
Cc: s47F ; CLARKE, Avinash
Subject: RE: Update on review of sunscreen ingredients [SEC=OFFICIAL]
Date: Monday, 13 January 2025 1:05:44 PM
Attachments: image002.png
image003.png
s22

Dear s22 ,

Happy new year! I hope you had a fun and relaxing holiday. I am writing to you all as I am unsure whether s22 is back from his extended leave.

Before I get into the information I have gathered so far, the questions asked in the first table do not appear appropriate for individual Sponsors. Information such as market share and 'stratification' by concentration etc. could not be done by individual companies, nor industry associations that do not have all Sponsors as their members.

A better approach may be to consider commercially available sales data that can provide sales information, then use the formulation information that the TGA holds to work out this information. There are several benefits to this approach:

1. The TGA will have a more robust set of data as the full spectrum of products will be capture, not just those companies willing to volunteer their information.
2. The sales information is also likely to be closer to the actual use volume than the manufacture/import data (member companies can more readily provide manufacture/import data).
3. Avoid duplicative information coming in from manufacturers and Sponsors.

I have attached sales data from mid-2023. I am working to see whether I can gain access to a more recent data set (such data is expensive and can be difficult to obtain). However, noting that product popularity and therefore sales fluctuates across time, the 2023 data should give the TGA good enough information to work out the answers to the questions in the first table.

With regard to the second table, the responses from members were not consistent across the board. Below is a summary of the information so far:

1. Most companies do not test every product for benzophenone (as there has been no requirement to do so locally nor globally).
2. One company batch tests most of their products, and some companies have been monitoring benzophenone levels.
    a. The company testing benzophenone levels do not have end of shelf-life data for all of their products that they test, as some products were relatively recently launched.
3. If benzophenone levels need to be established for all octocrylene containing products, the cost implications would include:
    a. Testing all retain samples that are likely to be in the hundreds (I do not currently have data on cost of testing). One company reported 200 separate formulations that

would need to be tested.

b. Question mark on what needs to happen with products that have been recently launched (depending on transition time to compliance) for end of shelf-life benzophenone levels.

As mentioned from the beginning of this process, it would be really useful to understand the project outline and timelines so that we can better communicate with our members on likely timings, regulation impact on businesses and whether there will be more thought given to transition if any new requirements are imposed. It would also be useful to understand whether there will be a cost/benefit analysis and public consultation given that some companies are not members of either Accord or CHP, and whether there may be trade (technical barriers to trade) notification that may need to occur.

I look forward to hearing back from you and better understanding the process.

Kind regards,
s47F

s47F
s47F
Accord Australasia Limited

PO Box 290 BROADWAY NSW 2007
Fusion C4.03, 22-36 Mountain Street
ULTIMO NSW 2007
Phone: 02 9281 2322
Fax: 02 9281 0366
Mobile: s47F
Email: coh@accord.asn.au
Website: http://accord.asn.au/

From: s22 @health.gov.au>
Sent: Tuesday, 12 November 2024 1:52 PM
To: s47F @accord.asn.au>
Cc: s47F @accord.asn.au>; CLARKE, Avinash <Avinash.CLARKE@Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: Update on review of sunscreen ingredients [SEC=OFFICIAL]

Dear s47F
Thank you for your kind words and well wishes.

I think your offer of assistance is excellent, and I would like to take you up on it now that we have

additional time.

As you know, we have ARTG information on sunscreens reported by sponsors, which includes product names and formulation details. However, this information does not reflect products that have been manufactured or are in supply, nor does it indicate the market share of certain products. It also does not provide details on pack sizes or label information regarding how they are marketed.

Therefore, it would be very useful if you could assist us by providing any data regarding homosalate, oxybenzone, and octocrylene/benzophenone. I believe this information would be of significant value in informing regulatory considerations before public consultation, rather than obtaining it during the consultation process.

I recognise that this information may be difficult to gather, but any data your members can provide would be helpful in informing our next steps. I've drafted a quick table below of what information I think could be useful.

It might be useful to discuss with CHP Australia to cover as many industry members and provide the same data to compare apples with apples. If you're happy to reach out to s47F to coordinate please let me know? Otherwise I can request this data separately from her.

Thank you again for your support.

s22
Sunscreen Taskforce
Complementary & OTC Medicines Branch
Medicines Regulation Division | Health Products Regulation Group
Australian Government Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: Level 1, 27 Sherger Drive, Fairbairn 2609
PO Box 100, Canberra ACT 2601, Australia

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Information	**Ingredient**		
	Homosalate	Oxybenzone	Octocrylene
% market share of all therapeutic sunscreens that contain each ingredient (products being manufactured and supplied, or comparative sales data?).			
Sunscreen range stratified by ingredient concentration, pack size, dose form, and directions for use (e.g. X % of products being supplied have <7.5% homosalate in 50mL dropper bottles are marketed for face only application in adults)			

Information	Ingredient
	Benzophenone
Any testing results on levels (ideally end of shelf life, including on existing retention samples) in existing sunscreens with octocrylene. Any plans to undertake testing?	
Number of products tested to demonstrate less than 383ppm benzophenone at end of shelf life. If so, what levels?	
Number of products tested demonstrating more than 383ppm benzophenone at end of shelf life. If so, what levels?	
Any information or manufacturing developments on improving stability of formulations to reduce degradation of octocrylene? E.g. is there a specific excipient that reduces degradation potential?	

From: s47F [redacted] @accord.asn.au>
Sent: Tuesday, November 12, 2024 1:03 PM
To: s22 [redacted] @health.gov.au>
Cc: s47F [redacted] @accord.asn.au>; CLARKE, Avinash <Avinash.CLARKE@Health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>
Subject: Re: Update on review of sunscreen ingredients [SEC=OFFICIAL]

Dear s22 [redacted]

Thank you for the update. We really appreciate the additional considerations. If we can be of any assistance in the risk consideration e.g. by providing information on formulations, product types, please let us know and we can canvass our members.

Just in case, I don't get a chance to speak to you before you go on leave, enjoy your extended leave!

Kind regards,

s47F [redacted]

s47F [redacted]

s47F [redacted]
Accord Australasia Limited

PO Box 290 BROADWAY NSW 2007

Fusion C4.03, 22-36 Mountain Street

ULTIMO NSW 2007

Phone: 02 9281 2322
Fax: 02 9281 0366
Mobile: s47F [redacted]
Email: coh@accord.asn.au

accord
hygiene, personal care & speciality products industry

Website: http://accord.asn.au/

From: s22 [redacted] @health.gov.au>
Sent: Tuesday, November 12, 2024 12:18 PM
To: s47F [redacted] @accord.asn.au>
Cc: s47F [redacted] @accord.asn.au>; CLARKE, Avinash <Avinash.CLARKE@Health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>
Subject: Update on review of sunscreen ingredients [SEC=OFFICIAL]

Dear s47F [redacted],

I wanted to provide an update on our next steps since our last discussion on sunscreens. The TGA is arranging seeking independent clinical advice regarding the sunscreen ingredient tox review and potential risks. This advice will help inform any future scheduling meeting discussions and appropriate public communication. To allow sufficient time to consider the issue carefully, we are not taking scheduling proposals to the March 2025 joint ACMS/ACCS scheduling meeting, but rather aiming to take this matter to the June 2025 meeting.

If there are any further developments or we have any further questions, we will continue to be in touch. In the meantime, we are working on a draft ARGS update to include guidance on use of the ASEM that we will share with you in the near future for review.

I also wanted to inform you that I will be on extended leave from 22 November. In my absence you can contact my colleagues s22 [redacted] and s22 [redacted] regarding these matters.

Best regards,

s22 [redacted]
Sunscreen Taskforce
Complementary & OTC Medicines Branch
Medicines Regulation Division | Health Products Regulation Group
Australian Government Department of Health and Aged Care
T: s22 [redacted] | E: s22 [redacted] @health.gov.au
Location: Level 1, 27 Sherger Drive, Fairbairn 2609
PO Box 100, Canberra ACT 2601, Australia

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Meeting Outcome Note

Sunscreen Working Group - Sunscreen excipient assessment fees

Date: 12 February 2025

Time: 9.30 am to 11 am

Location: TGA Fairbairn

External Participants

Participant	Organisation
s47F [redacted]	Accord
	Accord
	Accord
	Accord
	Consumer Healthcare Products Australia
	Consumer Healthcare Products Australia
	Consumer Healthcare Products Australia

TGA Participants

Name	Position
Nick Henderson	First Assistant Secretary, Medicines Regulation Division
Avinash Clarke	Assistant Secretary, Complementary & Over the Counter medicines Branch
s22 [redacted]	Acting Director, Complementary Medicines Evaluation Section
	Director, Business Improvement and Support Section
	Assistant Director, Complementary Medicines Evaluation Section
	Regulatory Legal Services Branch
	Regulatory Legal Services Branch

Discussion items

s22 [redacted]

- Planning required for potential outcomes of scheduling consideration of active sunscreen ingredients and the downstream effects on sunscreen supply.

Meeting Outcome

s22 [redacted]

d. Discussion and planning for potential scheduling decisions on ingredients

(i) Prior discussion on any proposed changes
(ii) Consideration given to market impacts
(iii) Implementation planning
(iv) Transition allowance

Action items

Industry to provide:

- s22 [redacted]
- Sunscreen market data
- s22 [redacted]

TGA to:

- s22 [redacted]
- [redacted]

- s22 [redacted]
- Provide plan for future activities related to sunscreens.
- Consider implementation planning and discussions with industry on scheduling changes.

s22

From: s47F @accord.asn.au>
Sent: Friday, 14 March 2025 1:45 PM
To: CLARKE, Avinash; HENDERSON, Nick; s47F ; s22 ; s47F ; s22 ; s22
Subject: RE: Sunscreen working group [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi Avi,

Thank you for the draft project plan. It appears that the regulation impact consideration will only occur after the decision is already made. Is this correct?

Will the decision makers have access to important information e.g. number of products impacted, impact of different transition times, etc. to inform them before they make their decision?

Kind regards,
s47F

From: CLARKE, Avinash <Avinash.CLARKE@Health.gov.au>
Sent: Friday, 14 March 2025 11:18 AM
To: HENDERSON, Nick <Nick.Henderson@health.gov.au>; s47F @accord.asn.au>; s47F s47F @accord.asn.au>; s22 @health.gov.au>; s47F @accord.asn.au>; s47F @chpaustralia.com.au>; s47F s47F @chpaustralia.com.au>; s47F @chpaustralia.com.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: Sunscreen working group [SEC=OFFICIAL]

Hi All,

As discussed – please see a draft project plan around scheduling of sunscreen ingredients. Appreciate any comments/suggestions.

s22

Thanks, Avi

Avinash Clarke
02 5132 1436

From: CLARKE, Avinash
Sent: Monday, 3 March 2025 12:46 PM
To: HENDERSON, Nick <Nick.Henderson@health.gov.au>; s47F @accord.asn.au>; s47F

s47F @accord.asn.au>; s22 @health.gov.au>; s47F @accord.asn.au>; s47F @chpaustralia.com.au>; s47F s47F @chpaustralia.com.au>; s47F @chpaustralia.com.au>; s22 @health.gov.au>; s22 @health.gov.au>

Subject: Sunscreen working group [SEC=OFFICIAL]

Hi All,

Apologies for the long delay. Please see attached draft outcomes/action items from last month's sunscreen meeting. We'll also endeavour to set up a future meeting series shortly.

Thanks, Avi

Avinash Clarke
Assistant Secretary
Complementary and Over the Counter Medicines Branch

Therapeutic Goods Administration
Australian Government Department of Health and Aged Care
T: 02 5132 1436 | E: avinash.clarke@health.gov.au

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s22

Doucment 7

Document 7

s22

Doucment 7

Document 7

From: ComTech Secretariat <ComTech.Secretariat@health.gov.au>
Sent: Thursday, 20 March 2025 9:18 AM
To: s47F >; s47F @regsolutions.com.au>; talktous@qualitymatterssafetymatters.com.au; Regulatory <regulatory@accord.asn.au>; s47F @accord.asn.au>; s47F s47F @chpaustralia.com.au>; s47F @chpaustralia.com.au>; s47F @cmaustralia.org.au; s47F @cmaustralia.org.au>; s47F s47F @cmaustralia.org.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>
Subject: Call for agenda nominations ComTech 15 [SEC=OFFICIAL]

Dear ComTech members,

The next ComTech meeting is scheduled to be held on Tuesday the 20th of May 2025.

If you have any agenda item topics for nomination, could you please send these to the ComTech Secretariat by the 28th of March.

Thank you.

Kind regards,
s22

Secretariat Support

Complementary and OTC Medicines Regulatory and Technical Forum

Email: ComTech.Secretariat@Health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606 Australia

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s22

From: CLARKE, Avinash
Sent: Friday, 14 March 2025 11:18 AM
To: HENDERSON, Nick; s47F s22
Subject: RE: Sunscreen working group [SEC=OFFICIAL]
Attachments: Scheduling of Sunscreen Ingredients - Proposed Project Plan (Draft).docx

Follow Up Flag: Follow up
Flag Status: Completed

Hi All,

As discussed – please see a draft project plan around scheduling of sunscreen ingredients. Appreciate any comments/suggestions.

Additionally, we are currently preparing a briefing paper for discussion at ComTech 15 – scheduled for 20 May 2025. We are still at project conceptualisation stage –it will be on further stratification of current IN ingredient application categories under section 26BD, including considering dermal ingredients that are demonstrated to not be absorbed and not react with the skin.

Thanks, Avi

Avinash Clarke
02 5132 1436

From: CLARKE, Avinash
Sent: Monday, 3 March 2025 12:46 PM
To: HENDERSON, Nick <Nick.Henderson@health.gov.au>; s47F @accord.asn.au>; s47F s47F @accord.asn.au>; s22 @health.gov.au>; s47F @accord.asn.au>; s47F @chpaustralia.com.au>; s47F s47F @chpaustralia.com.au>; s47F @chpaustralia.com.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: Sunscreen working group [SEC=OFFICIAL]

Hi All,

Apologies for the long delay. Please see attached draft outcomes/action items from last month's sunscreen meeting. We'll also endeavour to set up a future meeting series shortly.

Thanks, Avi

Avinash Clarke
Assistant Secretary
Complementary and Over the Counter Medicines Branch

Therapeutic Goods Administration
Australian Government Department of Health and Aged Care
T: 02 5132 1436 | E: avinash.clarke@health.gov.au

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Scheduling of Sunscreen ingredients

Proposed project plan

March 2025

Potential Scheduling process timeframes and key information

Date	Activity	Comments
By Mid-April 2025	**Develop Public engagement material** Develop a series of social media posts for consumers and health professionals on the proposed changes and what it means.	Aligned with publishing of the public notice of the scheduling proposal.
Early/Mid-April 2025	**Stakeholder communications** Provide embargoed information and resources to key stakeholders including government, industry, peak bodies and health professionals (e.g. Dear Healthcare Professional letter), prior to publication of the safety reviews.	To assist stakeholders to be prepared with their media activities.
Mid-April 2025	**Publish consultation on proposed scheduling changes** Publish: • TGA media release • Sunscreen ingredients hub (landing page) • Safety review reports • Public notice and consultation on scheduling proposal referred to the Joint ACCS-ACMS – June 2025	Consultation closes in May 2025
	Public engagement Disseminate tailored resources for specific audiences via: • Media platforms • Facebook, Instagram, LinkedIn and X • TGA email newsletters to industry, health professionals and consumers • Direct stakeholder emails	
17-19 June 2025	Expert advisory committee meeting (Joint ACCS-ACMS)	

Date	Activity	Comments
September 2025[i]	Public notice and consultation on the interim decision	Anticipated public submission closing date - October 2025
October/November 2025	**Consideration of Regulatory impacts** Submission of Preliminary Impact Assessment form to the Office of Impact Analysis (OIA) – only if interim decision proposes increase in regulatory controls If decided by the OIA preparation of an Impact Analysis. OIA will advise the level of analysis required.	A call for further information may be made if an impact analysis is required.
TBC	Publishing of Final decision and Impact Analysis	The timing of the public notice of the final decision will be dependent on the level of impact analysis required.
TBC	Implementation of Final decision in the Poisons Standard.	The implementation date will need to consider an appropriate transition period for the market to comply with any changes.

[i] Anticipated administrative timeframes – subject to the drafting of the interim decision and the level of engagement during the initial consultation.