Data Supplement

Airbrush

Barley

Re-Review

EXPERT PANEL MEETING
June 16-17, 2022

Commitment & Credibility since 1976

Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Monice M. Fiume MMF
Senior Director, CIR
Date: June 6, 2022
Subject: airbrush boilerplate – Wave 2

Per the instructions of the Panel at the March Panel meeting, CIR staff developed an airbrush boilerplate for inclusion in all reports that addresses the fact that airbrush application of cosmetic products is not assessed by the Expert Panel for Cosmetic Ingredient Safety; the boilerplate language was included in all reports that were issued following the March meeting. Subsequently, the CIR Science and Support Committee (SSC) submitted comments on that language. (see *CIRSSCcomments_AirbrushBoilerplate_Wave2_062022*)

Upon review of these comments, CIR staff revised the boilerplate language that was initially used, generally accepting the suggestions made by the CIR SSC, but with a few modifications. This updated version of the airbrush boilerplate language is included in the Cosmetic Use section and the Discussion section of all reports that were submitted to the Panel for review at the June meeting.

Because this is a new boilerplate for inclusion in all reports, it is attached for the Panel's review. As stated above, this is a slightly modified version of what was suggested by the CIR SSC. Both the boilerplate as written and included in the June reports and the language suggested by the CIR SSC are provided for your review as a side-by-side comparison, and the differences are highlighted (*comparison_AirbrushBoilerplate_Wave2_062022*). Also included in that comparison is the language that was originally developed and used in the reports issued after the March meeting. Because there was significant revision to most of the initial paragraph that is used in the Cosmetic Use section, the differences between the version that was included in the March reports and the language suggested by the CIR SSC are not highlighted.

Personal Care Products Council
Committed to Safety, Quality & Innovation

TO: Bart Heldreth Ph.D.
Executive Director – Cosmetic Ingredient Review

FROM: CIR Science and Support Committee of the Personal Care Products Council

DATE: April 18, 2022

SIBJECT: Comments Airbrush Boilerplate Language as Presented in the March 2022 Post-Meeting Announcement

The CIR Science and Support Committee (CIR SSC) appreciates the opportunity to comment on the airbrush boilerplate language as presented in the March 2022 post-meeting announcement.

Our key concerns are:

1. The boilerplate language suggests that FDA cosmetic product categories provide information about the use of cosmetic products and ingredients that is not actually included. With a few exceptions, the cosmetic product categories listed in 21CFR part 720.4 do not indicate how the products are applied, or "the intended uses of a cosmetic ingredient". PCPC surveys are also based on the FDA cosmetic product categories with a few subclassifications about type of application, e.g., spray or not spray, for some FDA cosmetic product categories.
2. To avoid the suggestion that airbrush applicators used for cosmetics are medical devices, the terminology "airbrush delivery systems" should be used rather than "airbrush devices".
3. The boilerplate language should make it clear that habits and practices data and particle size information on airbrush products are needed to estimate exposure (rather than risk or safety).

We suggest the following revised language.

In the Cosmetic Use section:

"The safety of the cosmetic ingredients addressed in this assessment is evaluated based on data received from the US Food and Drug Administration (FDA) and the cosmetics industry on the expected use of these ingredients in cosmetics and does not cover their use in airbrush delivery systems. Data are submitted by the cosmetic industry via the FDA's Voluntary Cosmetic Registration Program (VCRP) database (frequency of use) and in response to a survey conducted by the Personal Care Products Council (Council) (maximum use concentrations). The data are provided by cosmetic product categories based on 21CFR Part 720. For most cosmetic product categories, 21CFR Part 720 does not indicate type

of application and therefore, airbrush application is not considered. Airbrush delivery systems are within the purview of the US Consumer Product Safety Commission (CPSC), while ingredients, as used in airbrush delivery systems, are within the jurisdiction of the FDA. Airbrush delivery systems for cosmetic application have not been evaluated by the CPSC, nor have the use of cosmetic ingredients in airbrush delivery systems been evaluated by the FDA. Moreover, no consumer habits and practices data are publicly available to evaluate the exposure associated with this use type and therefore, airbrush application of cosmetic products is not assessed by CIR."

When discussing potential safety concerns raised by specific routes of exposure, we suggest the following revised paragraph:

"Additionally, although products containing some of these ingredients may be marketed for use with airbrush delivery systems, this information is not available from the VCRP or the Council survey. Without information regarding the frequency and concentrations of use these ingredients (and without consumer habits and practices data related to this use technology), the data are insufficient to evaluate the exposure resulting from cosmetics applied using airbrush delivery systems."

Rather than a paragraph, we suggest that the following sentence be added to the end of the inhalation paragraph of the Discussion section.

"As indicated in the respiratory exposure resource document and in the Cosmetic Use section of this report, airbrush application of cosmetic products is not assessed by CIR."

Language as included in June reports	**CIR SSC suggested language**	**original version, in post-March 2022 reports**
Cosmetic Use section – initial paragraph The safety of the cosmetic ingredients addressed in this assessment is evaluated based on data received from the US Food and Drug Administration (FDA) and the cosmetics industry on the expected use of these ingredients in cosmetics, and does not cover their use in airbrush delivery systems. Data are submitted by the cosmetic industry via the FDA's Voluntary Cosmetic Registration Program (VCRP) database (frequency of use) and in response to a survey conducted by the Personal Care Products Council (Council) (maximum use concentrations). The data are provided by cosmetic product categories, based on 21CFR Part 720. For most cosmetic product categories, 21CFR Part 720 does not indicate type of application and, therefore, airbrush application is not considered. Airbrush delivery systems are within the purview of the US Consumer Product Safety Commission (CPSC), while ingredients, as used in airbrush delivery systems, are within the jurisdiction of the FDA. Airbrush delivery system use for cosmetic application has not been evaluated by the CPSC, nor has the use of cosmetic ingredients in airbrush technology been evaluated by the FDA. Moreover, no consumer habits and practices data or particle size data are publicly available to evaluate the exposure associated with this use type, thereby preempting the ability to evaluate risk or safety. Therefore, airbrush application of cosmetic products is not assessed by the Panel.	Cosmetic Use section – initial paragraph The safety of the cosmetic ingredients addressed in this assessment is evaluated based on data received from the US Food and Drug Administration (FDA) and the cosmetics industry on the expected use of these ingredients in cosmetics and does not cover their use in airbrush delivery systems. Data are submitted by the cosmetic industry via the FDA's Voluntary Cosmetic Registration Program (VCRP) database (frequency of use) and in response to a survey conducted by the Personal Care Products Council (Council) (maximum use concentrations). The data are provided by cosmetic product categories based on 21CFR Part 720. For most cosmetic product categories, 21CFR Part 720 does not indicate type of application and therefore, airbrush application is not considered. Airbrush delivery systems are within the purview of the US Consumer Product Safety Commission (CPSC), while ingredients, as used in airbrush delivery systems, are within the jurisdiction of the FDA. Airbrush delivery systems for cosmetic application have not been evaluated by the CPSC, nor have the use of cosmetic ingredients in airbrush delivery systems been evaluated by the FDA. Moreover, no consumer habits and practices data are publicly available to evaluate the exposure associated with this use type and therefore, airbrush application of cosmetic products is not assessed by CIR.	Cosmetic Use section – initial paragraph – original version The safety of the cosmetic ingredient addressed in this assessment is evaluated based on data received from the US Food and Drug Administration (FDA) and the cosmetics industry on the expected use of these ingredients in cosmetics. Use frequencies of individual ingredients in cosmetics are collected from manufacturers and reported by cosmetic product category in the FDA Voluntary Cosmetic Registration Program (VCRP) database. The cosmetic product categories named in the VCRP database indicate the intended uses of cosmetic ingredients, and are identified in 21 CFR Part 720. Data are submitted by the cosmetic industry in response to a survey conducted by the Personal Care Products Council (Council) of maximum reported use concentrations, also by product category. Neither the categories provided by the VCRP, nor those provided by the Council survey, include a designation for use via airbrush application. Airbrush devices, alone, are within the purview of the US Consumer Product Safety Commission (CPSC), while ingredients used in airbrush devices are within the jurisdiction of the FDA. As airbrush technology use for cosmetics has neither been evaluated by the CPSC, nor the use of cosmetic ingredients in airbrush technology by the FDA, no US regulatory authority has evaluated the safety of this delivery methodology for cosmetic ingredients. Moreover, no consumer habits and practices data are available to evaluate the risks associated with this use type.

Language as included in June reports	CIR SSC suggested language	original version, in post-March 2022 reports
Further in the Use Section - when discussing potential safety concerns raised by specific routes of exposure Additionally, although products containing some of these ingredients may be marketed for use with airbrush delivery systems, this information is not available from the VCRP or the Council survey. Without information regarding the frequency and concentrations of use of these ingredients (and without consumer habits and practices data or particle size data related to this use technology), the data are insufficient to evaluate the exposure resulting from cosmetics applied via airbrush delivery systems.	Further in the Use Section - when discussing potential safety concerns raised by specific routes of exposure Additionally, although products containing some of these ingredients may be marketed for use with airbrush delivery systems, this information is not available from the VCRP or the Council survey. Without information regarding the frequency and concentrations of use of these ingredients (and without consumer habits and practices data related to this use technology), the data are insufficient to evaluate the exposure resulting from cosmetics applied using airbrush delivery systems.	Further in the Use Section - when discussing potential safety concerns raised by specific routes of exposure Additionally, although products containing this ingredient may be marketed for use with airbrush technology, this information is not available from the VCRP or the Council survey. Without information regarding the frequency and concentrations of use of this ingredient (and without consumer habits and practices data related to this use technology), the data are insufficient to evaluate the safety thereof in airbrush applications.
Discussion **Always as part of the inhalation paragraph, included in all reports:** As indicated in the respiratory exposure resource document and in the Cosmetic Use section of this report, airbrush application of cosmetic products in not assessed by the Panel. **separate paragraph, when instructed to be used by the Panel because of known/suspected airbrush uses:** The Panel acknowledged that some cosmetic ingredients are used in products marketed for airbrush application. However, the available data are insufficient to make a determination of safety for use of these ingredients in products that may be incidentally inhaled when applied using airbrush delivery systems. The Panel's respiratory exposure resource document (https://www.cir-safety.org/cir-findings) notes that airbrush technology presents a potential safety concern, and that no data are available for consumer habits and practices thereof. Thus, the data do not support the safety the ingredients named in this report if applied via airbrush delivery systems.	Discussion **As part of the inhalation paragraph:** As indicated in the respiratory exposure resource document and in the Cosmetic Use section of this report, airbrush application of cosmetic products is not assessed by CIR.	Discussion **as appropriate, when instructed to be used by the Panel:** The Panel acknowledged that some cosmetic ingredients are used in products marketed for airbrush application. However, the available data are insufficient to make a determination of safety for use of these ingredients in products that may be incidentally inhaled when applied using airbrush devices. The Panel's respiratory exposure resource document (https://www.cir-safety.org/cir-findings notes that airbrush technology presents a potential safety concern, and that no data are available for consumer habits and practices thereof. Thus, the data do not support the safety the ingredients named in this report if applied via airbrush technology.

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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Christina L. Burnett, Senior Scientific Writer/Analyst, CIR
Date: June 6, 2022
Subject: Safety Assessment of Barley-Derived Ingredients as Used in Cosmetics – Wave 2

The Council has provided CIR with unpublished data on Hordeum Vulgare Stem Water, which are attached herein for the Panel's review (*data_Barley_Wave2_062022*). The data includes a technical data sheet with a few physical and chemical properties, and a manufacturing process chart. Additionally, a fragrance allergen analysis indicated that none of the common fragrance allergens of concern in Europe were detected in Hordeum Vulgare Stem Water.

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Personal Care Products Council
Committed to Safety, Quality & Innovation

Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Carol Eisenmann, Ph.D.
Personal Care Products Council

DATE: May 18, 2022

SUBJECT: Hordeum Vulgare Stem Water

Anonymous. 2021. Technical sheet: Hordeum Vulgare Stem Water.

Anonymous. 2019. Fragrance allergen analysis Hordeum Vulgare Stem Water.

Anonymous. 2022. Method of manufacture Hordeum Vulgare Stem Water.

[redacted]

TECHNICAL SHEET

[redacted]

DESCRIPTION

Type of product	Distilled Water
Botanical name	Hordeum vulgare L.
Plant part	Culms
Extraction ratio	22.3%
Preservative	Sodium benzoate 0.3%, citric acid 0.06%
INCI	Hordeum Vulgare Stem Water*, Sodium Benzoate, Citric Acid *Ingredient from organic farming
Organic mention	Certified as 99.64% organic by Ecocert Greenlife according to COSMOS standard available at http://COSMOS.ecocert.com

ORGANOLEPTIC SPECIFICATIONS

Appearence	Liquid
Colour	Colorless to very clear yellow
Odor	Characteristic

PHYSICAL AND CHEMICAL SPECIFICATIONS

pH (at 20° C) internal method	[4.0 ; 5.0]

MICROBIOLOGICAL SPECIFICATIONS

Aerobic mesophilic flora at 30 ° C NF ISO 21149	< 100 cfu/ml
Yeast and moulds standard NF ISO 16212	< 100 cfu/ml

STORAGE

Shelf life	1 year in original packaging, sealed.
Storage conditions	The product is stable in its original packaging, at a temperature stable and moderate, protected from light air and moisture.
Comments	Use by date is not guaranteed after opening

GLUTEN

Has a gluten concentration below the limit of detection (<5 ppm) (analysis completed in 2011)

Fragrance Allergen Analysis - Hordeum Vulgare Stem Water

[redacted]

[redacted]

REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL - COMMISSION REGULATION (EU) No 344/2013 - COMMISSION REGULATION (EU) No 483/2013

Issue date: 15/02/2016 Revision date: 24/06/2019 Supersedes: 15/02/2016 Version: 1.1

ALLERGENS						
Reference number	Name of common ingredients glossary	CAS-No.	EC-No.	Allergen % in product		Comments
				% in w/w in the concentrate	% in w/w for a usage at -%	
45	Benzyl Alcohol	100-51-6	202-859-9	Not detected	Not detected	
1380	3- and 4-(4-Hydroxy-4-methylpentyl) cyclohex-3-ene-1-carbaldehyde (HICC)	51414-25-6 31906-04-4	257-187-9 250-863-4	Not detected	Not detected	
90	alpha-Isomethyl ionone	127-51-5	204-846-3	Not detected	Not detected	
67	Amyl cinnamal	122-40-7	204-541-5	Not detected	Not detected	
74	Amylcinnamyl alcohol	101-85-9	202-982-8	Not detected	Not detected	
80	Anise alcohol	105-13-5	203-273-6	Not detected	Not detected	
85	Benzyl benzoate	120-51-4	204-402-9	Not detected	Not detected	
81	Benzyl cinnamate	103-41-3	203-109-3	Not detected	Not detected	
75	Benzyl salicylate	118-58-1	204-262-9	Not detected	Not detected	
83	Butylphenyl methylpropional	80-54-6	201-289-8	Not detected	Not detected	
76	Cinnamal	104-55-2	203-213-9	Not detected	Not detected	
69	Cinnamyl alcohol	104-54-1	203-212-3	Not detected	Not detected	
70	Citral	5392-40-5	226-394-6	Not detected	Not detected	
86	Citronellol	106-22-9 26489-01-0	203-375-0 247-737-6	Not detected	Not detected	
77	Coumarin	91-64-5	202-086-7	Not detected	Not detected	
71	Eugenol	97-53-0	202-589-1	Not detected	Not detected	
92	Evernia furfuracea extract	90028-67-4	289-860-8	Not detected	Not detected	

[redacted]

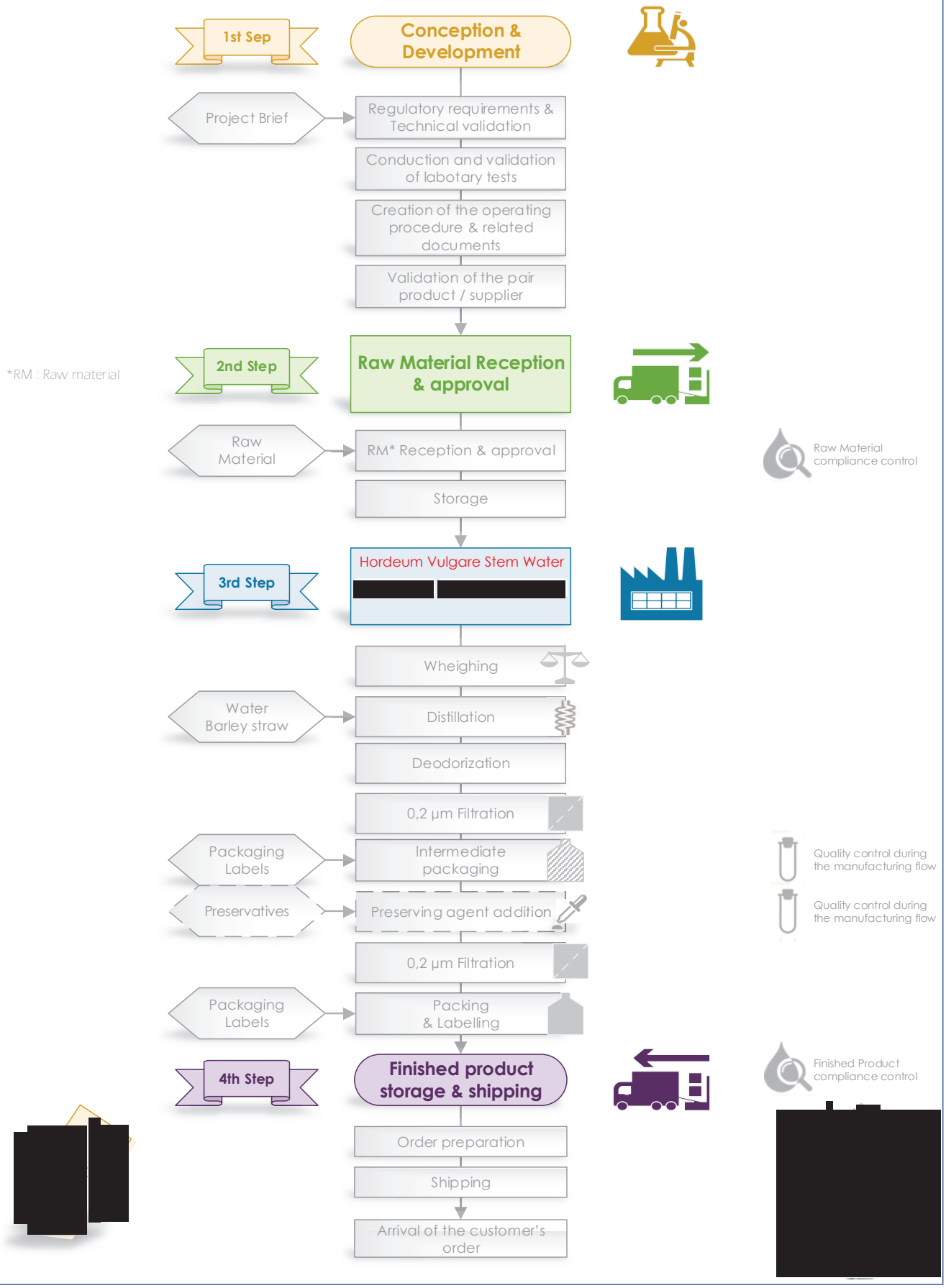
91	Evernia prunastri extract	90028-68-5	289-861-3	Not detected	Not detected	
82	Farnesol	4602-84-0	225-004-1	Not detected	Not detected	
78	Geraniol	106-24-1	203-377-1	Not detected	Not detected	
87	Hexyl cinnamal	101-86-0	202-983-3	Not detected	Not detected	
72	Hydroxycitronellal	107-75-5	203-518-7	Not detected	Not detected	
79	Hydroxyisohexyl 3-cyclohexene carboxaldehyde	51414-25-6 31906-04-4	257-187-9 250-863-4	Not detected	Not detected	
73	Isoeugenol	97-54-1 5932-68-3	202-590-7 227-678-2	Not detected	Not detected	
88	Limonene	5989-27-5	227-813-5	Not detected	Not detected	
84	Linalool	78-70-6	201-134-4	Not detected	Not detected	
89	Methyl 2-Octynoate	111-12-6	203-836-6	Not detected	Not detected	

[redacted]

PROCESS

Hordeum Vulgare Stem Water [redacted] Manufacturing chart

[redacted]



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Monice M. Fiume MMF
Senior Director, CIR
Date: June 6, 2022
Subject: Re-Review Strategy – Wave 2

According to Part D, Section 47, of the *Cosmetic Ingredient Review Procedures & Support to the Expert Panel for Cosmetic Ingredient Safety*:

(d) The Expert Panel may, in its discretion or at the request of the Chair of the Steering committee, consider a re-review of any Final Report.

(1) Consideration of such a re-review may be based upon new data and information **or the passage of substantial time** since publication of the Final Report.
(2) If the Expert Panel concludes that a re-review is warranted, such re-review shall follow the process established in these procedures for the initial review of the ingredient.
(3) If the Expert Panel concludes, after considering any new data and information that have become available since publication of the Final Report, that a re-review is not warranted, the Expert Panel may issue a statement of its reasons for that conclusion in a Re-Review Summary for publication.
(4) The Executive Director shall give advance public notice that the Expert Panel is considering the re-review of an ingredient and invite public comment and participation.

The agreed upon "substantial time" for consideration of a re-review has generally been a minimum of 15 years.

Consideration for re-review applies both to safety assessments that have been issued only once, as well as those that have been previously reconsidered. Consequently, the number of reports for re-review has increased substantially. In order to ease the burden on both the Panel and the CIR staff, a methodology has been adopted for the evaluation of safety assessments that are due for re-review, and that is the strategy that been used in all re-review documents submitted to the Panel for the June meeting.

For each safety assessment being considered for re-review, the CIR staff conducted an exhaustive search of the world's literature for studies dated 5 years prior from the original publication, forward. A historical overview, the search strategy used, and a synopsis of notable new data, as well as a table comparing original and current frequency and concentration of use, were prepared. It is this information that was provided to the Panel with the original mailing for the June meeting. Additionally, it should be noted that if ingredients that were originally included in the safety assessment have been re-reviewed in a more recent report, those ingredients are not included in the current document. Any instances where this is the case are noted in the submission.

The purpose of this strategy is to provide the Panel with enough information to determine whether the existing conclusion still applies, or if a re-review is warranted, without exhausting the resources of the staff or the Panel for the initial consideration of re-review. If upon examination of these documents the Panel determines a re-review is warranted, a Draft Amended Report will be presented at an upcoming meeting. Likewise, if the Panel chooses to not re-open the safety assessment, a Re-review Summary will be prepared

Does the Panel find this an acceptable strategy for the consideration of safety assessments due for re-review?