

INTERNATIONAL COOPERATION ON COSMETICS REGULATION



Report of the ICCR Working Group¹:

Considerations on Acceptable Trace Level of 1,4-Dioxane in Cosmetic Products

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¹ Brazil ANVISA joined the ICCR Steering Committee in 2014, and did not participate in the report of this ICCR Working Group.

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NOTICE: This report is the result of the work of the ICCR Traces Working Group (WG)¹. It contains recommendations for trace 1, 4-dioxane levels in cosmetic products. These recommendations are developed according to the "Principles for the Handling of Traces of Impurities and/or Contaminants in Cosmetic Products."

This recommendation may be used by industry and by ICCR countries and regions within the boundaries of their legal and institutional constraints.

Introduction:

1,4-Dioxane is an impurity that may be present in trace amounts in some cosmetic products. 1, 4-Dioxane itself is not used as a cosmetic ingredient but can form as a by-product during the manufacturing process of certain ethoxylated cosmetic ingredients. The mandate of the ICCR Traces WG is to establish and recommend appropriate trace levels based on considerations of scientific risk assessment, good manufacturing practices, technical feasibility, and appropriate analytical methods², keeping in mind the ultimate goal of consumer safety.

1. Exposure routes for cosmetics:

The primary exposure routes for 1, 4-dioxane impurities in cosmetics are inhalation and dermal absorption, primarily following use of skin moisturizers, shampoos, conditioners, and body washes.

1,4-Dioxane is a volatile impurity that readily evaporates into the air, which reduces the amount of the impurity that is likely to be inhaled. For the same reason, the dermal absorption of 1, 4-dioxane is minimal and the dermal route, in general, involves a substantially lower absorption factor than the oral route. These aspects contribute to the conservatism of the assessment described below.

2. Safety considerations:

Studies at the U.S. National Cancer Institute found an association between 1, 4-dioxane and cancer in animals when 1,4-dioxane was administered in high levels in

animal feed. There have been several assessments of the safety of 1, 4-dioxane in cosmetic products. A summary of these safety assessments is provided below and corresponding safety margins are summarized in Table 1 (see section 5).

- a. In Australia, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) published an assessment of 1,4-dioxane³. A NOAEL of 10 mg/kg/day based on liver tumors in rats was used in the assessment. Exposure to several consumer products (cosmetics/toiletries and detergents) was calculated with the highest potential exposure attributed to a hand dishwashing liquid (0.72 µg/kg/day assuming a 1, 4-dioxane level of 30 ppm and 2 washes per day). It was then assumed that a person might use up to 10 consumer products per day, resulting in a worse case systemic exposure from consumer products of 7 µg/kg/day. This report concludes that, “compared with a NOAEL of 10 mg/kg/day, the above worse case assumption of a systemic exposure of 7 µg/kg/day (from consumer products) represents a margin of safety (MOS) of about 1500. The presence of 1,4-dioxane (up to 30 ppm) as an impurity in consumer products is therefore not considered to pose a significant health risk to the general public.”
- b. In 2010, Health Canada conducted a screening assessment of 1,4-dioxane as part of Chemicals Management Plan (CMP)⁴.

Using a 1, 4-dioxane impurity level of 75 ppm, adult women represented the population with the highest potential exposure, and skin moisturizer represented by far the largest exposure source via both inhalation and dermal routes. Health Canada identified 9.6 mg/kg/day as the lowest chronic exposure level at which no tumor formation was observed and an oral NOAEL for non-neoplastic effects (liver toxicity) in experimental animals (Kociba et al. 1974). This value was compared to 0.0012 mg/kg/day, which was the aggregate estimated intake range from daily-use cosmetic products (i.e., shampoo, conditioner, shower gel and skin moisturizer – taking into account dermal and inhalation exposures combined). This resulted in margins of exposure of greater than 8000, which were considered to be adequately protective. The assessment concluded that 1, 4-dioxane is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health. The “margin of exposure” (MOE) is used for risk assessment. The MOE is calculated as the NOAEL divided by the estimated exposure. The MOE value is compared with the uncertainty factor for species or individual differences. MOE > uncertainty factor indicates that the risk is not at a level that is of concern. MOE <

uncertainty factor indicates that the risk is at a level that is of concern and there is a need to take countermeasures.

- c. 1, 4-Dioxane was evaluated by the European Chemicals Bureau (ECB) in 1999. Based on exposure scenarios from the occurrence of 1, 4- Dioxane in shampoo (50 ppm), baby lotion (10 ppm) and dishwashing liquid (30 ppm), the margins of safety between the inhalation exposure estimates and the NOAEL of 400 mg/m³ are all >>10,000. The MOSs between the dermal exposure estimates and the calculated dermal NOAEL of 20 mg/kg bw/day are far greater than 1,000.

Taking into account intra- and inter-species differences, the non-genotoxic properties of the substance and the use of NOAELs from chronic studies, these margins of safety (MOS) indicate no concern for consumers by inhalation and dermal exposure.

The European Commission's independent scientific advisory committee (Scientific Committee on Consumer Safety (SCCS)) performed a critical evaluation of the carcinogenic risk in relation to the presence of traces of 1,4-dioxane in cosmetics². The SCCS does not support the NOAEL approach for 1,4-dioxane based on the available data and therefore calculated the life-time cancer risk (LCR).based on the T25 and linear extrapolation. This approach is in line with the EU chemicals legislation and the DG SANTE scientific committees risk assessment methodology. It is recognised that linear extrapolation may in some cases result in overestimation of risks at low exposures. The SCCS considers a LCR of 10⁻⁵ as a tolerable risk level but notes that the decision of an acceptable/tolerable or less than serious risk is in the end a risk management decision.

- d. In Japan, the risk assessment for 1,4-dioxane by the National Institute of Advanced Industrial Science and Technology (AIST) assessed hazards from a cross-sectional review of previous hazard assessments and a review of the literature⁵.

A value of 10 mg/kg/day was used as an oral exposure NOAEL, as indicated from the hazard assessment above, and 83 mg/m³ was used as an inhalation exposure NOAEL. When the latter value is converted into a value in terms of

² SCCS/1570/15 15 December 2015,

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_194.pdf.

body weight per day, it becomes 25 mg/kg/day. A value of 1000 was used as an uncertainty factor for both oral and inhalation exposures.

For inhalation exposure in the general population, the MOE is calculated as 350,000 using the 95th percentile (0.072 µg/kg/day). This greatly exceeds the uncertainty factor (1000), and is interpreted as “the risk is not at a level that is of concern and no need to take countermeasures”.

In oral and dermal exposures in the general population, the MOE is calculated as 130,000 using the 95th percentile of oral and dermal exposure (0.079 µg/kg/day). This greatly exceeds the uncertainty factor (1,000), and is interpreted as “the risk is not at a level that is of concern and no need to take countermeasures”.

3. Current Situation in the ICCR Jurisdictions:

The ICCR Traces WG has assessed the current situation of 1, 4-dioxane control for cosmetics in ICCR countries/regions and is aware that there are differing approaches and levels for 1, 4-dioxane.

Canada: 1, 4-Dioxane was added to Health Canada’s Cosmetic Ingredient Hotlist in 2010. Therefore, 1, 4-dioxane should not be intentionally added to cosmetics legally sold in Canada, although residual levels are known to exist in many cosmetic/personal care and consumer products.

As current levels of 1, 4-dioxane in products were considered not to pose undue risk to Canadians, no regulatory action (i.e. concentration levels) was deemed necessary. However, the Consumer Product Safety Directorate of Health Canada will continue to monitor dioxane levels in Canadian cosmetic and personal care products.

Europe: The Cosmetics Regulation (EC) No 1223/2009³ states in recital (37) that "in order to ensure product safety, prohibited substances should be acceptable at trace levels only if they are technologically inevitable with correct manufacturing processes and provided that the product is safe".

In addition, article 17 (Traces of prohibited substances) states that "The non-intended presence of a small quantity of a prohibited substance, stemming

³ OJ L 342, 22.12.2009, p. 59.

from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3.” Article 3 establishes that that any cosmetic product placed on the European Unions' market must be safe.

In the Cosmetics Regulation, 1, 4-dioxane is listed in Annex II as a prohibited substance.

Japan: Japan has not set a level for trace admissible levels of 1, 4-dioxane in finished products or in raw materials. Japan approaches the control of levels of 1,4-dioxane in cosmetic products through raw materials.

United States: The FDA has not established or recommended a specific level for 1, 4-dioxane impurities in cosmetics. FDA has provided guidance to manufacturers alerting them to the health concerns and how to minimize 1, 4-dioxane by means of a process called "vacuum stripping" at the end of the polymerization process. This information is currently available in “1,4-Dioxane A Manufacturing Byproduct”.

4. Maximum Tolerable Levels:

The available safety assessments pertaining to 1,4-dioxane are summarized in the following table:

Table 1: Summary of Safety Assessments for 1,4-dioxane

Jurisdiction	Daily exposure level	Rationale/Calculation	Comments
Canada – CMP assessment	85 ug/day (dermal + inhalation exposure combined)	0.0012 mg/kg-bw per day [Aggregate estimated intake range from daily-use products (intake from dermal and inhalation exposure). See Table 7b of CMP assessment] <u>Note:</u> <i>100 % inhalation absorption</i> <i>3.4% dermal absorption (Marzulli et al. 1981).</i>	Comparing the daily exposure level (0.0012 mg/kg/day) to 9.6 mg/kg-bw per day, which is the oral exposure level at which no tumour formation was observed and oral NOAEL for non-neoplastic effects (liver toxicity) in experimental animals (Kociba et al. 1974), gives a margin of exposure of 8000.

		In CMP assessment, adult female assumed to be 70.9 kg – multiplying these numbers gives a daily exposure level of 85 ug/day.	Comparing the daily exposure level (0.0012 mg/kg/day) to 16 mg/kg-bw per day, which is the oral LOAEL for liver lesions in experimental animals (Yamazaki et al. 1994; JBRC 1998c) gives a margin of 13 300.
Europe	<p>1) ECB: 217 µg/day (dermal + inhalation exposure from shampoo, baby lotion and dishwashing liquid combined)</p> <p>651 µg/day (as above, in a very worst case scenario for shampoo and dishwashing liquid)</p>	<p>1) ECB: 3 scenarios are considered for adult consumer exposure from shampoo (I) baby lotion (IIA) and dishwashing liquid (III). In the light of dioxane content data available at that time (2002) the dioxane contents are assumed respectively equal to 50 mg/kg for shampoos 10 mg/kg for baby lotions (both assumed as worst case assumptions) and 30 mg/kg for dishwashing liquid. For scenarios I and III, very worst cases are also considered where the dioxane levels for shampoo and dishwashing liquid are respectively 300 and 100 mg/kg.</p> <p>The total internal dose from the scenarios I, IIA and III occurring together is 3.342 µg/kg bw/day (10.02 µg/kg bw/day for the very worst case scenarios). Multiplied by a body weight of 65 kg this gives 217 µg/day (651 for the very worst case scenarios).</p> <p>For children, exposure is calculated only from baby lotions (Scenario IIB), yielding a dose of 3.05 µg/kg bw/day, which multiplied by 8 kg body weight gives 24.4 µg/day.</p> <p><i>Note: 100 % absorption for inhalation and 50% for dermal.</i></p> <p>See EU Risk Assessment Report, pages 49-53 and Appendix A)</p>	<p>1) ECB: When comparing the oral NOAEL 10 mg/kg bw/day with the total internal doses for scenario I (0.92 µg/kg bw/day), IIA (3.05 µg/kg bw/day), IIB (2.29 µg/kg bw/day), III (0.132 µg/kg bw/day), and for the combined scenario (3.342 µg/kg bw/day) the MOS-values are all >>3,000.</p> <p>Even (<i>the very worst case</i>) scenario (10 µg/kg bw/day) would result in MOS-value ≥1,000 when compared to the oral NOAEL of 10 mg/kg bw/day. Hence, also in this very worst case, there would be no concern for consumers after inhalation and dermal exposure.</p>

	2) SCCS: 87 µg/day (aggregate dermal exposure from all cosmetics; actual exposure expected to be 'considerably less'	2) SCCS: 17.4 g/day value used for aggregate cosmetic exposure; systemic dose of 87 ug/day calculated assuming all products contain 10 ppm 1,4-dioxane and dermal absorption is 50%. Total exposure acknowledged to 'probably be considerably less' based on existing analytical data ('about 2/3 (65%) of all cosmetic products analyzed contained <=1 ppm')	2) SCCS concludes that the data do not allow for the identification of a threshold, and a non-threshold mode of action is therefore assumed, despite considering 1,4-dioxane to be non-genotoxic. Life-time cancer risk (LCR) is determined by linear extrapolation using T25 value. LCR of 10 ⁻⁵ is calculated to represent exposure of 0.92 µg/kg bw.day, equal to 55 µg assuming 60 kg body weight. LCR at 10 ppm limit 'should be considered tolerable'; target level of ≤ 10 ppm 'should be phased in over a short transition period'
Australia	420 ug/day	Assuming that a person might use up to 10 consumer products per day, as the worst case scenario, with systemic exposure levels of 0.72 ug/kg/day from each product, the daily exposure would be about 7 ug/kg/day. Taking this value and multiplying by a body weight of 60 kg person, will obtain 420 ug/day (NICNAS, 1998).	Compared with a NOAEL of 10 mg/kg/day, the above worst case assumption of a systemic exposure of 7 µg/kg/day (from consumer products) would represent a safety margin (MOS) of about 1500. The presence of 1,4-dioxane (up to 30 ppm) as an impurity in consumer products is therefore not considered to pose a significant health risk to the general public.
Japan	0.072 ug/kg/day (inhalation exposure) 0.079 ug/kg/day (oral +dermal exposure combined) 4.3 µg/day	In assessment of general population, distribution of exposures was estimated using Monte Carlo simulation for each route of intake via various exposure media (drinking water, the use of detergent products and air). See AIST Risk Assessment Document Series No.9 1,4-dioxane (2009).	Compared with inhalation NOAEL of 10 mg/kg/day and oral NOAEL of 25 mg/kg/day, the MOE for inhalation exposure that was calculated using 95 percentile is 35000, and the MOE for oral and dermal exposure is 130000, respectively, The MOEs greatly exceed the uncertainly factor of 1000, indicating that the risk is not at a level of concern, and no need to take countermeasure.

An assessment by the state of California under their Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)⁶ is not included in Table 1 because available documentation suggests that the assessment was not based on an exposure level. Specifically, 30 ug/day represents a cancer-risk level extrapolated from animal data which is not an exposure estimate. The No Significant Risk Level (NSRL) is the daily intake level calculated to result in one excess case of cancer in an exposed population of 100 000, assuming lifetime (70-year) exposure at the level in question. Based on the combined incidence of hepatocellular adenomas and carcinomas in female B6C3F1 mice, the California assessment selected a cancer potency of 0.027 (mg/kg/day)⁻¹. The intake level associated with a 10⁻⁵ risk of cancer is 30 micrograms per day for regulatory purposes (OEHHA, 1990). The equation that was used is:

$$I = \frac{R * BW}{q \text{ human}}$$

where I = intake, R = cancer risk, q human = theoretical cancer potency for humans, BW = body weight of 70 kg. The intake level was calculated to be 26 ug/day and was rounded up to 30 ug/day for regulatory purposes (based on a document via email correspondence (please see referenced citation, pages 28-29).

5. Consideration of reasonably achievable levels of 1,4-dioxane in cosmetic products:

Since the possibility of 1,4-dioxane contamination of cosmetics has been known for more than 40 years, there exists analytical data from many different sources that can be used to consider what is currently a reasonably achievable level. An overview of the testing of raw materials and finished products by different investigators was recently published.⁷

a. Reports released by the U.S. Food and Drug Administration:

- i. FDA 2001⁸: FDA published a peer reviewed summary report on their experience analyzing cosmetic raw materials and finished products over a period of 16 years using two different methods of analysis. The results of analysis of cosmetic products is summarized as follows:

Year	No. of products	No. of products containing 1,4-dioxane	1,4-Dioxane, ppm	
			Range	Average
1981 ^a	11	8	2–279	50
1982 ^a	3	2	2–36	19
1983 ^a	11	6	1–8	2
1984 ^a	3	0	0	0
1992 ^b	34	31	5–141	41
1993 ^b	12	7	50–112	79
1994 ^b	27	6	20–107	45
1995 ^b	6	3	42–90	74
1996 ^a	10	7	6–34	14
1997 ^a	10	6	6–34	19

^a Products analyzed by the azeotropic distillation method.

^b Products analyzed by the solid-phase extraction method.

- ii. FDA 2010:⁹ FDA presented a poster at the 2010 Association of Official Analytical Chemists providing data recently collected for 35 products analyzed using the solid-phase extraction method. The level of detection reported is 1.0 ppm. These results are summarized as follows:

Total products tested:	35
Reported as ND:	28 (80%)
Reported 0.1 – 1.0 ppm	0
Reported 1.1 – 5.0 ppm:	2 (~6%)
Reported 5.1 – 10 ppm:	2 (~6%)
Reported 10.1 – 25.0 ppm	3 (~8%) (highest 11.6 ppm)
Reported > 25.1 ppm:	0

ND = None detected

b. Reports Released by Non-Government Organizations:

- i. Report released by the Organic Consumers Association¹⁰ presenting results from analysis of 99 products. This report includes 12 non-cosmetic products such as dish washing detergents and household cleaners. The non-cosmetic products have been excluded from this evaluation. The level of detection is 0.2 ppm even though some of the results reported are less than this value. The distribution of results for the cosmetic products are as follows:

Total products tested:	87 Products
ND	51
0.1 – 1.0 ppm	6
1.1 – 5.0 ppm	15
5.1 – 10.0 ppm	9
10.1 – 25.0 ppm	5
> 25.1 ppm	1 (32.2 ppm)

- ii. Report from the Campaign for Safe Cosmetics¹¹ on the results of analysis of 48 baby and children's products for 1,4-dioxane. The report includes a general description of the analytical method but does not present a level of detection. The distribution of results are as follows:

Total products tested:	48 Products
ND	16
0.1 – 1.0 ppm	10
1.1 – 5.0 ppm	15
5.1 – 10.0 ppm	3
10.1 – 25.0 ppm	3
> 25.1 ppm	1 (35.0 ppm)

- c. The following table reflects consolidation of the data from the 170 products reported:

Levels Reported	Number of Products	Percent of Total
ND	95	56 %
0.1 – 1.0 ppm	16	9 %
1.1 – 5.0 ppm	32	19 %
5.1 – 10.0 ppm	14	8 %
10.1 – 25.0 ppm	11	6 %
> 25.1 ppm	2 (32.2, 35.0 ppm)	1 %

These results show that all recent analytical results are below 50 ppm. Further, 96 percent of the results are below 25 ppm and 90 percent at 10 ppm or less

6. Framework for Recommendation:

In developing the recommended target level for 1,4-dioxane in cosmetics and personal care products, the ICCR Traces WG has taken into account the following factors:

- a. The WG has applied the As Low As Reasonably Achievable (ALARA) concept as described in "Principles for the handling of traces of impurities and/or contaminants in cosmetic products". In this report, it is noted that for cosmetics "ALARA means those levels of traces that can be achieved through reasonable and practical approaches to control of raw materials and the manufacturing process. It does not encompass extraordinary efforts beyond these ordinary steps." In this recommendation, the WG proposes that the recommendation of a reasonably achievable target level captures the intent of ALARA.
- b. The reasonably achievable level presented in section 8, below, takes into account information about the levels of 1,4-dioxane available from publications and other reports available to the WG. In determination of what is reasonably achievable, the in-market data on 1,4-dioxane levels in finished cosmetic products from various studies and applications of general GMP principles were taken into consideration in addition to consultation with the industry representatives participating on the ICCR Traces WG.
- c. The WG considered exposure and the comparison of exposure levels to tolerable levels available from regulatory authorities.
- d. With the exception of the SCCS assessment which recommends a lower level, results available in both the published scientific literature and in other reports available to the WG are below accepted margins of safety. Therefore, the level recommended by the Traces WG is based on the established reasonably achievable value which is based on the available analytical data.

7. Recommendation:

With the exception of the SCCS assessment which recommends a lower level, 1, 4-dioxane levels reported in the literature are within accepted safety margins. The ICCR Traces WG recommends setting a target level for 1,4-dioxane in finished cosmetic products in two phases. The two-phased recommendation is proposed to acknowledge the reduction of 1, 4-dioxane levels in finished products to 25 ppm that has been

achieved by 96% of tested products, and the recognition that 10 ppm can be reached using current methods of control.

Further, the ICCR Traces WG notes that target levels for 1, 4-dioxane in finished products may be achieved through control systems that rely on monitoring of raw materials and/or finished products (see 9(b)) and the Appendix). In developing this recommendation, the ICCR WG notes the following points:

- a. The WG considered the data available on the levels of 1,4-dioxane in finished cosmetic products published over many years.
- b. The WG recognizes that this data was developed independently by different sources using different methods.
- c. The WG notes that the values presented demonstrate a clear downward trend from the earliest reports to those published most recently.
- d. The WG acknowledges this downward trend as an indication of the efforts of cosmetic product manufacturers to control the levels of 1,4-dioxane in finished products through either selection of appropriate raw materials and/or monitoring of finished products.
- e. The WG notes that a summary of the data that has been published since 2001 shows that the values are all below 50 ppm, 96 % are below 25 ppm, and 90% are 10 ppm or less. This constitutes evidence that the levels of 1, 4-dioxane can be controlled and maintained at low levels, which are considered "reasonably achievable".
- f. With the exception of the SCCS assessment which recommends a lower level, the WG notes that all of the levels reported in the recent literature are within accepted margins of safety as determined by assessment of exposure and calculation of risk (based on available safety assessments shown in section 5). The WG further notes that, although the data come from different sources, there appears to be a high degree of consistency among the results.
- g. The WG notes that the reasonably achievable levels apply to the finished cosmetic product and that the method of control of either raw materials or the finished product is acceptable.
- h. The WG emphasizes that, in no case, should currently achievable levels be allowed to reach higher levels.

The WG recommends that the target level of trace 1,4-dioxane in cosmetics is achieved in two phases by industry:

- 1. Phase 1: A target level of less than or equal to 25 ppm in finished products.**
 - 2. Phase 2: A target level of less than or equal to 10 ppm in finished cosmetic products should be phased in over a suitable transition period.**
- Different jurisdictions have taken different approaches for controlling 1, 4-dioxane in cosmetics. In some cases specific levels have not been established because 1, 4-dioxane levels in cosmetics that have been reported from various sources are within accepted margins of safety. The ICCR Traces WG emphasizes the importance of taking into account these differences and notes that the target levels described above should include a suitable transition period to be set by each ICCR jurisdiction or applied by individual private companies (See Appendix).¹² The European Commission, based on the opinion of the SCCS, recommends that for the EU market a target level of less than or equal to 10 ppm of 1,4-dioxane in finished cosmetic products should be phased in over a short transition period.

8. Points to Consider:

The following points are important in considering the recommended 1,4-dioxane level and approaches to ensuring that the levels are controlled:

- a. With the exception of the SCCS assessment, the recommended 2-phased target levels are within accepted safety margins. These target levels appear achievable based on the available monitoring data.¹³
- b. 1, 4-dioxane in the finished product is effectively controlled through (1) monitoring of the raw materials used to formulate the product and/or (2) monitoring the finished product. It is not necessary to test all raw materials and production lots where there is in place adequate control of raw materials and/or the manufacturing process.
- c. All of the analytical results available to the WG are within accepted margins of safety. While the data does not suggest that 1, 4-dioxane presents a public health risk, the WG notes that there are several benefits to acceptance and publication of this recommendation. These are summarized as follows:

- i. The publication of this recommendation can serve as a guide for all raw material suppliers and product manufacturers to help ensure that the current level of control is maintained both within ICCR jurisdictions as well as other global jurisdictions.
 - ii. The publication of this recommendation can guide entities that are contemplating supplying raw material to the cosmetics market as to steps that are needed regarding quality and composition.
 - iii. The publication of this recommendation can serve as a model for those jurisdictions that are contemplating establishment of controls and regulations.
 - iv. In light of the recurring questions regarding the safety of cosmetic products that might contain trace levels of 1, 4-dioxane, this recommendation might serve to provide a useful and aligned reference regarding safety and controls within the ICCR jurisdictions.
 - v. As noted above, the proposed 2-phased recommendation reflects the general reduction of trace 1, 4-dioxane levels in finished products (25 ppm) that has been achieved, and the recognition that 10 ppm can be consistently reached using current methods of control. With the exception of the one established by the SCCS, the target levels of 25 and 10 ppm are both within accepted margins of safety and, accordingly, reflect the application of ALARA and raw material and finished product quality.
- d. The presence of 1, 4-dioxane is determined in the finished product using an appropriate method of analysis, usually a headspace gas chromatographic analysis. Description of the current analytical approaches for cosmetics is available in the referenced Technical Guidance document¹⁴. The method should follow the ISO standard validation criteria for analytical results in cosmetics (ISO 12787).

In closing, the ICCR Traces WG wishes to note that meeting any recommendation of the WG does not exempt manufacturers (or importers, distributors, etc) from their legal obligations in their respective jurisdictions.

APPENDIX I: Steps for Reducing 1, 4-Dioxane Levels in Cosmetic Products

In order to align products to a uniform level of 1,4-dioxane, all responsible persons (for example manufacturers, distributors and importers) may need to take steps that impact on their current processes for control of raw material and the manufacturing processes. Due to the complexity of raw material sourcing and control and manufacturing (including labeling), sudden and unexpected changes in requirements can be very disruptive. Considering the global nature of today's markets, suggested or required changes that affect the supply chain can be especially difficult and complex to control and rapidly resolve. Changes that require reformulation may also present difficulties because of all of the steps necessary for product development, raw material selection and control, manufacturing and labeling (if reformulation is necessary).

Considering these factors, the steps that may be necessary to achieve the recommended level for 1, 4-dioxane in products include, but are not limited to, the following:

- **Raw Material Suppliers** - Raw material suppliers apply established systems and controls that ensure the safety and functionality of their products for their customers. Sourcing of raw material must take into account the manufacturing process, handling, storage, specifications and customer agreements. In any case, it will be helpful for the supplier to know that the cosmetic manufacturer will conduct its evaluation for the finished good. This will alert them whether or not to specify 1,4-dioxane levels in the raw material. Any change in the attributes of a raw material requires assessment and possible modification of the systems and controls for the ingredient.
- **Raw Material Selection** - In considering the product type, formulation and performance, cosmetic product manufacturers invest considerable research and investigation into the ingredients that are selected and the manufacturing process that converts the individual raw materials into the desired product. The control of the content of 1,4-dioxane in finished product requires knowledge and control of the individual ingredients, their use levels in the product and the final composition of the product. Changes in any of the many steps involved in the selection of raw materials can significantly impact and possibly require changes in these steps.

- Product Manufacturing - Product manufacturing requires that all systems and controls are in place and working, i.e. functioning, properly. This includes raw material specifications and qualification, manufacturing parameters, packaging and monitoring systems. Due to the complexity and interconnection of these systems and controls, especially in the raw material supply chain, actions that alter existing processes can have significant impact on product manufacturing. The revision of product manufacturing procedures can take considerable time to identify reasonable alternative approaches, adequate controls and product functionality.

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¹ This report for ICCR has been prepared by the ICCR Working Group on Traces :

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² By appropriate it is meant that the method is reliable and reproducible to the highest quality standards such as methods considered as validated by the respective jurisdictions.

³ See http://www.nicnas.gov.au/publications/car/pec/pec7/pec7_full_report_pdf.pdf.

⁴ The final assessment can be found at http://www.ec.gc.ca/substances/ese/eng/challenge/batch7/batch7_123-91-1_en.pdf.

⁵ http://www.aist-riss.jp/projects/RAD/download01/download01.cgi?RISS_1_4-dioxane_e The summary of the document is available at http://unit.aist.go.jp/riss/crm/mainmenu/1,4-Dioxane_Executive%20Summary_e.pdf and the article is in Environmental Sciences, 13 (1), 43-58 (2006). http://122.249.91.209/myukk/free_journal/Download.php?fn=ES609_full.pdf

⁶ See <http://oehha.ca.gov/water/pals/pdf/pal14dioxan.pdf>. The state of California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) is not a U.S. federal law and applies only to products sold in the state.

⁷ T.K.G. Mohr (with J.A. Stickney and W.H. DiGuseppi), Environmental Investigation and Remediation: 1,4-Dioxane and Other Solvent Stabilizers, CRC Press/ Taylor & Francis Group, Boca Raton, FL (2010), Chapter 6, pp. 263-325.

⁸ Roderick E. Black, Fred J. Hurley and Donald C. Havery, Journal of the AOAC International, v. 84, 666 - 670, 2001.

⁹ Hardy J. Chou, Perry G. Wang, Wanlong Zhou, and Alexander J. Krynitsky, 124th AOAC Annual Meeting, 2010, posted titled " Determination of 1,4-Dioxane in Cosmetic Products".

¹⁰ Report from the Organic Consumers Association, March 14, 2008, Consumer Alter available at <http://www.organicconsumers.org/bodycare/DioxaneRelease08.cfm>.

¹¹ Campaign for Safe Cosmetics, March 2009, Report titled "No More Toxic Tub" available at http://www.safecosmetics.org/downloads/NoMoreToxicTub_Mar09Report.pdf.

¹² Elements suitable to be considered for defining the transition period would be regulatory requirements applicable in each jurisdiction, 1,4-dioxane levels respectively in products currently on the market and reasonably achievable under good manufacturing practices, and steps for reducing 1,4-dioxane levels in cosmetics products. Summary information about all these elements is included in the present recommendation, based on the best knowledge of the Traces WG.

¹³ For example, a report issued by the Organic Consumers Group in 2008 found levels of ND – 32.2 ppm (average = 2.4 ppm) in cosmetics (see <http://www.organicconsumers.org/bodycare/DioxaneAlert080314.pdf>). A report released by the Campaign for Safe Cosmetics in 2009 found levels of ND – 35 ppm (average = 3.0 ppm) (see http://www.safecosmetics.org/downloads/NoMoreToxicTub_Mar09Report.pdf).

¹⁴ Technical Guidance Document on Determining 1,4-Dioxane in Cosmetics, Cosmetic Europe, March 2012