REPORT FOR THE
INTERNATIONAL COOPERATION ON COSMETICS REGULATION

ICCR-7: Traces Working Group: Considerations on Acceptable Lead Levels in Cosmetic Products (Excluding products used in the oral cavity)

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NOTICE: This report is the result of the work of the ICCR Traces Working Group. It contains recommendations for trace lead levels in cosmetic products. These recommendations were developed in accordance with the ICCR document *Principles for Handling Trace Materials*.

The recommendations may be used as a relevant technical contribution by industry and by ICCR members when considering appropriate steps within the boundaries of their legal and institutional constraints.

1. Introduction

Lead is a ubiquitous toxic metal. Human exposure is common resulting from its natural occurrence in the environment and its many uses including production of lead batteries, production of lead alloys, use in soldering materials, shielding for x-ray machines, and in the manufacture of corrosion and acid resistant materials used in the building industry. Human lead exposure had declined significantly in recent years due to the phase out of lead as a gasoline additive and as a paint additive, and the discontinuation of lead-soldered food cans (NTP, 2012). Human exposure is mainly via food and water, with some via air, dust, and soil (ATSDR, 2007; EFSA, 2010).

Lead toxicity has been extensively studied and has been associated with a wide range of health effects, including effects on the cardiovascular, renal, immune, reproductive, and neurological systems in children and adults. The most sensitive endpoints have been identified as developmental toxicity in young children and cardiovascular effects and nephrotoxicity in adults (ATSDR, 2007; EFSA, 2010; NTP, 2012). A recent review by an international panel under the auspices of the U.S. National Toxicology Program (NTP) focused on health effects of low levels of lead based on the outcomes of recent epidemiology studies. The review concluded that lead toxicity occurs at levels lower than previously recognized (NTP, 2012).

The occurrence of lead in -rocks, soil and water results in its presence in raw materials and finished products in all industries including the cosmetics industry. Trace levels of lead in cosmetics are expected to be primarily inorganic in form, consistent with what occurs in the environment (ATSDR, 2007; EFSA, 2010). Lead should not be intentionally added to cosmetic products. However, because of the ubiquitous presence of lead in the environment, it is not practical to completely eliminate its presence in daily exposures. The ICCR Traces Working Group's (WG) goal is to establish and recommend appropriate levels for trace materials in cosmetics based on considerations of reasonably achievable levels, scientific risk assessment, good manufacturing practices, technical feasibility, and appropriate[1] analytical methods, keeping in mind the ultimate goal of consumer safety. Annex I lists references used in developing the recommendation.

[1] 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.

2. Exposure routes for cosmetics

For the purpose of this document, dermal exposure is expected to be the most significant route of exposure for cosmetic products, considering normal or reasonably foreseeable conditions of product use. Oral exposures can occur through products such as lipsticks, mouthwashes, and toothpastes. The dermal absorption of lead contained in mineral substances 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.

Products intentionally used in the oral cavity, such as mouthwashes and toothpastes, may be considered in a separate work item for the ICCR Traces WG.

3. Maximum Tolerable Levels

In order to put the issue of trace levels of lead into context, the ICCR Traces WG has referenced the maximum tolerated exposure to lead using the FDA Provisional Total Tolerable Intake (PTTI) values[2]. Based on this, the group has calculated the lead levels that would be required to approximate the PTTI with sole exposure from cosmetic products (therefore excluding lead intake from food, air, water, etc) (see Annex II). For additional context, comparisons of exposure via cosmetics for products with lead levels of 10 ppm and 20 ppm to the PTTI are provided in Annex III. Other reference points, such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Provisional Tolerable Weekly Intake (PTWI) shown below (in 9f) could also be used for similar evaluation, but the PTTI was chosen as the most conservative and represents total exposure from all sources of lead[3]. For additional perspective, exposure from cosmetics was compared to estimates of mean dietary exposure and with lower end values of the dietary exposure range. It is acknowledged that current tolerable intake levels are the subject of continued evaluation and current guidance values may be changed at some point in the future.

[2] See http://www.fda.gov/Food/FoodSafety/FoodContaminantsAdulteration/Metals/Lead/ucm115941.htm for more information about the PTTI.

[3] FDA memorandum "Clarification of Terminology Used in the Development of the Provisional Total Tolerable Intake Levels for Lead" dated November 18, 1991 referenced in Federal Register proposal 59 FR 5363 dated February 4, 1994. See also Carrington and Bolger in Regulatory Toxicology and Pharmacology, **16**, 265-272 (1991)

As discussed below, the ICCR Traces WG notes that the existing lead level of 20 ppm followed in some jurisdictions is considered tolerable by these jurisdictions, and also as compared with estimated exposures and available tolerable levels.

4. Current Situation in the different ICCR jurisdictions

Lead must not be intentionally added to cosmetic products, although its presence as an impurity is permitted provided that such presence is technically unavoidable in good manufacturing practice, and that the product does not cause damage to health under normal or reasonably foreseeable conditions of use. The ICCR Traces WG has assessed the current situation of lead control for cosmetics in ICCR countries/regions and is aware that different approaches and levels exist.

- Japan approaches control of lead through a 5 - 50 ppm level on raw materials and does not impose a specified level on the finished product. For example, the upper level of lead in titanium dioxide (TiO2) is 50 ppm and, if TiO2 is used in sunscreen at a concentration of 25%, a level of 12.5 ppm might be found in the finished products in this scenario.
- In the U.S., there is no current level for trace lead levels in finished products, although lead acetate is an approved color additive for coloring hair. Color additive ingredients have specifications for lead, generally at the 10 or 20 ppm level for lead. The level of lead in the finished product will vary depending on the amount in the raw material and could theoretically approach 20 ppm.
- In the European Union, a specific harmonized level has not been set for lead traces in finished products, although the Federal Institute for Risk Assessment of Germany issued a recommendation to level the lead impurities content to 20 ppm for most cosmetic products, and to 1 ppm for toothpaste.
- Canada has established guidance for impurities, setting a level of 10 ppm lead for finished cosmetic products.
- There may also be requirements in other jurisdictions that are unknown to the ICCR Traces WG.

5. WG Framework for Recommendation: In developing the recommendation in (8) below, the ICCR Traces WG has taken into account the following factors:

    a. The reasonably achievable level should be safe. Comparison of exposure levels to established tolerable levels available from regulatory authorities (see 9e below) should be considered. As further referenced below (9f), the JECFA concluded that no threshold of lead toxicity would be established. However, JECFA considered that any health risk that would be expected to occur at the lower end of the current dietary exposure estimates would be negligible. These exposure levels should also be taken into account, to ascertain whether the exposure estimates discussed in this recommendation of this report are comparable with these negligible levels.

    b. In light of concerns about chronic lead toxicity, it is acknowledged that current tolerable exposure levels set by regulatory authorities,- mainly based on oral exposure - may be subject to revision at some point in the future. The present evaluation focuses on products which are intended to be applied topically. Since systemic absorption of lead following dermal application is known to be low compared to oral bioavailability, the risk-based approach defined in this report is within safe levels.

    c. With deference to the recognized safe trace levels, the “As Low As Reasonably Achievable” (ALARA) principle must be a key element evaluated in this case, especially due to the safety concerns and uncertainty around chronic lead toxicity as described above. ALARA levels reflect quality of the raw materials and manufacturing practices, and are normally below levels related to safety criteria and may differ by manufacturer and region. They are part of a continuing process and can evolve over time, even within a company.[4]

    d. The setting of a reasonably achievable level should take into account information about the levels of lead in raw materials and finished products available from scientific publications and other sources.

    e. The acceptance of a target level for lead in cosmetic products (excluding products used in the oral cavity) is intended to set a reference level for use

[4] See the ICCR Traces WG “Framework for the handling of trace substances in cosmetic products”. The framework document for traces describes ALARA as “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.”

by manufacturers and regulatory authorities. The finding of lead in a product above the target level should not necessarily be considered as automatically triggering either allowance or removal of the product from the market.

f. All decisions to be taken should be compatible with the laws, policies, rules, regulations and directives of the respective administrations and governments and may require the final approval by senior levels of management at a later date in order to allow their operational implementation or transposition into practice[5].

6. Scope of Recommendation

The ICCR Traces WG generally recommends that the setting of target levels for trace materials consider a single level for all product types. In the case of lead, the assessment described in this document only addresses cosmetic products (excluding products used in the oral cavity). In order to complete the assessment for lead, the ICCR has agreed to assess lead in toothpaste and mouthwashes as a separate work item for the Traces WG.

7. Considerations for Recommendation

The ICCR Traces WG presents the following points to consider and recommendation for a target level for lead in cosmetic products (excluding products used in the oral cavity):

a) Available testing of finished cosmetic products finds that lead levels are generally 10 ppm or less[6], with some at higher levels.[7] Therefore, it

[5] Taken from the ICCR Terms of Reference in effect at the date of this document.

[6] European Commission Joint Research Centre (JRC) Technical Note N° 65914. P. Piccinini, M. Piecha and S. Fortaner Torrent, "Results of European Survey on Lead in Lipsticks" EUR 24886 EN: ISBN 978-92-79-18552-6; ISSN 1831-9424 (online); doi:10.2788/3600

[7] A Report titled “Determination of Pb in cosmetics in Japanese market,” dated November 29, 2010 and submitted by the Japan Cosmetic Industry Association showed that four of 51 products tested exceeded 10 ppm and two of those exceeded 20 ppm. All four were foundation products. All other products contained less than 10 ppm lead. MHLW’s summary of analyses of ~ 250 lip and dermal products manufactured worldwide is in draft and will be added when completed. Products included lipsticks, foundations, cheek colors, and eye products. Preliminary results show that almost all products contained less than 10 ppm lead. Specifically, 3/66 foundation products were greater than 10 ppm with one greater than 20 ppm. One out of 57 eyeliner products was greater than 20 ppm.

is considered that 10 ppm represents an achievable level in most cases. However, it is acknowledged that impurity levels in raw materials may vary significantly, and therefore suggesting a level of 10 ppm may pose challenges in certain jurisdictions.

b) Calculation of exposure and relative contributions to the PTTI using total lead values likely represents a maximum possible exposure and in most cases is considered an over-estimation of actual exposure (see 9e).

c) The above mentioned calculations, which likely represent maximum possible exposure levels, yield values comparable with those considered by JECFA as acceptable to prevent health concerns both when carried out under the assumption of 10 and 20 ppm lead in the finished product (See 9f).

d) Available analytical methodology used to determine lead levels referenced in this report generally determines total lead content and not merely biologically available lead.

e) In the specific case of lead, where possible health effects remain under evaluation, the ICCR Traces WG emphasizes the importance of both safety and ALARA considerations in this recommendation.

8. Recommendation

(1) Based on the findings of the ICCR Traces WG, trace levels of lead in finished cosmetic products (excluding products used in the oral cavity), should be kept below a target level of less than or equal to 10 ppm total lead, using a lead control system (through raw materials or finished products) described in section 4.

(2) For products that are found to contain trace amounts of lead in quantities greater than 10 ppm, it is recommended that steps be taken by individual companies and/or regulatory authorities, over a reasonable and specified period of time, to lower the total lead content

Two other studies have shown that some eye shadows have lead levels exceeding 10 ppm. Al-Saleh (2009) found two samples above 10 ppm and one above 20 ppm. Sainio (2000) found two above 10 ppm but each was less than 20 ppm.

to 10 ppm or less. An overview of the technical and organizational implications of these steps is provided in Annex IV.

Note: Once the recommended target for trace levels of lead is met, it should be maintained or improved over time.

9. Additional Points to Consider: The following points are important in considering the recommendations presented in this report intended to establish a target level for lead impurities and for ensuring that the levels are controlled:

a) The lead in the finished product can be 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 are in place adequate controls of raw material and of the manufacturing process.

b) Annex IV of this document: "Steps for Reducing Lead Content in Cosmetic Products (excluding products used in the oral cavity)" provides information relevant to achieving the recommended levels for lead impurities in cosmetic products.

c) The lead is determined as total lead in the product based on scientifically sound method(s) leading to validated results.

d) The sample exposure assessment below is calculated using a total amount of lead of 10 or 20 ppm in the finished product (other levels could also be used for this calculation). In fact, the lead contained in products is expected to be inorganic and, as such, only a fraction of the lead present is likely available for exposure (see Annex III).

e) For illustration purposes, the ICCR Traces WG compared the PTTI, which is meant to include lead exposure from all sources (air, water, food, products, etc., which mostly occurs following oral and/or inhalation exposure), with dermal exposure from cosmetics alone. This comparison defines the relative contribution of exposure from cosmetics containing 10 ppm or 20 ppm lead to the currently defined tolerable daily intake from all sources (see Annex III).

i. **Young children** (use of shampoos and body lotions)

10 ppm: 0.080 ug Pb/day is ~ 1.3 % of the PTTI (6 ug Pb/day for small children).

20 ppm: 0.160 ug Pb/day is ~ 2.7 % of the PTTI (6 ug Pb/day for small children).

ii. **Adults** (total exposure of adults to lead from cosmetic products, excluding products used in the oral cavity):

Pregnant and Lactating Women:

10 ppm: 0.75 ug Pb/day is ~ 3.0 % of the PTTI (25 ug Pb/day) for for pregnant and lactating women.

20 ppm: 1.50 ug Pb/day is ~ 6.0 % of the PTTI (25 ug Pb/day) for for pregnant and lactating women.

Adult Women:

10 ppm: 0.75 ug Pb/day is ~ 1.0 % of the PTTI (75 ug Pb/day) for adult women.

20 ppm: 1.50 ug Pb/day is ~ 2.0 % of the PTTI (75 ug Pb/day) for adult women.

The comparisons above include an assumption that all cosmetics, including those not containing color additives, contain lead at a hypothetical 10 ppm or 20 ppm lead level.

f) Other organizations have also considered acceptable exposure levels for lead, such as the World Health Organization. The Provisional Tolerable Weekly Intake (PTWI) was set in 1993 by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) at 25 µg/kg/wk for people in all age groups. For a 60 kg person, the PTWI translates to intake of ~214 µg/day, which is considerably higher than FDA's PTTI values. However, in a recently published opinion of the European Food Safety Authority (EFSA) and a summary report of the 73rd JECFA meeting, the panels concluded that the PTWI of 25 µg/kg body weight was no longer appropriate as a tolerable level.

For the purposes of the ICCR Traces WG, consideration of levels that are reasonably achievable and currently considered tolerable for human health is considered a more realistic approach for developing a recommendation for cosmetic products than trying to come to a definitive conclusion on "safe" levels for lead.

In order to validate how the above discussed exposure estimates (in 8e) from cosmetics compare with the lower end values of the dietary exposure range (0.03 μg/kg bw/day and 0.02 μg/kg bw/day for infants and adults, respectively) considered at the 73rd JECFA meeting and indicated as associated with negligible health risks, the following calculations were made.

i. **Young children** (use of shampoos and body lotions)

10 ppm: 0.080 ug Pb/day is ~ 44 % of JECFA lower end value (0.18 ug Pb/day [0.03 ug /kg/day X 6 kg bw] for small children).

20 ppm: 0.160 ug Pb/day is ~ 90 % of JECFA lower end value (0.18 ug Pb/day for small children).

ii. **Adults** (total exposure of adults to lead from cosmetic products (excluding products used in the oral cavity):

Pregnant and Lactating Women:

10 ppm: 0.75 ug Pb/day is ~ 42 % of JECFA lower end value (1.8 ug Pb/day [0.03 ug /kg/day X 60 kg bw]) for pregnant and lactating women.

20 ppm: 1.50 ug Pb/day is ~ 83 % of JECFA lower end value (1.8 ug Pb/day) for pregnant and lactating women.

Adult Women:

10 ppm: 0.75 ug Pb/day is ~ 62 % of JECFA lower end value (1.2 ug Pb/day [0.02 ug /kg/day X 60 kg bw])) for adult women.

20 ppm: 1.50 ug Pb/day is ~ 125% of the JECFA lower end value (1.2 ug Pb/day) for adult women.

In order to provide additional context, the values calculated for cosmetics were compared to estimates of mean dietary exposure available from Europe, the U.S. and Canada. EFSA (2010) estimated exposure to lead based on 94,126 analyses of lead levels in food commodities and tap water covering the period from 2003 to 2009. Lead dietary exposure for average adult consumers in 19 European countries ranged from 0.36 to 1.24 µg/kg body weight per day (lower bound for country with lowest average exposure – upper bound for country with highest average exposure). Therefore, assuming an average body weight of 60 kg, these average intake values would result in

lead exposure ranges for average adult consumers ranging from 21.6 µg/day to 74.4 µg/day. Data from the U.S. 1990-1991 Total Diet Survey indicate a range of dietary lead intake from 1.8 to 4.2 µg/day for all age groups combined (126 and 294 µg/day for a 70 kg person, respectively). More recent data in the U.S. come from the results of National Human Exposure Assessment Survey (NHEXAS) studies conducted by U.S. EPA, with results showing a mean dietary intake of lead of 0.25 µg/kg per day, or 17.5 µg/day for a 70 kg adult from lead in water and food (Thomas et al., 1999). Finally, daily dietary intake of lead estimated form a 1986 – 1988 Canadian Survey was 24 µg/day for all ages (Dabeka and McKenzie, 1995).

In summary, the most recent average daily dietary lead exposure estimates range from 17.5 µg/day to 74.4 µg/day, while adult exposure to lead from cosmetics assuming all products contain 10 ppm lead is 0.75 µg/day. On this basis, it is demonstrated that exposure to lead in cosmetics would represent between 1.0% and 4.3% of dietary exposure. In this comparison, the lead values for food are based on analytical data, whereas the cosmetic values represent worst-case assumptions.

The ICCR Traces WG wishes to note that meeting a recommendation of the WG does not exempt manufacturers/importers from their legal obligations in their respective jurisdictions.

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Annex II – Cosmetic Products (excluding mouthwash and toothpaste)

Lead Content calculated to reach the FDA's PTTI[8] -

Exposure[9]	***Young Children (PTTI = 6 ug Pb/day)***	***Pregnant/Lactating Women (PTTI = 25 ug Pb/day)***	***Adult Women (PTTI = 75 ug Pb/day)***
Dermally Applied Cosmetics	2.65 g/day[10]	15.03 g/day	15.03 g/day
Percutaneous Absorption of Lead[11]	0.3 %	0.3%	0.3%
Bioavailability of Lead once absorbed[12]	100%	100%	100%
Amount of lead in **dermally applied cosmetics** calculated to reach the PTTI[13]	~ 750 ppm	~556 ppm	~ 1667 ppm
Lipstick applied daily	N/A[14]	0.057 g/day	0.057g/day
Ingestion of Lipstick[15]	N/A	75 %	75 %
Bioavailability of Lead once ingested[16]	N/A	70 %	70 %
Amount of lead in **lipsticks** calculated to reach the PTTI[17]	N/A	833 ppm	2500 ppm
To reach the PTTI: Lead in each dermally applied cosmetic and lipstick product [18]	**750 ppm**	**333 ppm**	**1000 ppm**

[8] Re: Preparations for ICCR-IV: For discussions of the PTTI, etc. see June 12, 2010 "ICCR Traces Work Group: Discussion Paper for LEAD - Prepared by the Personal Care Products Council"

[9] Exposure information is based on SCCS's evaluation (Table 3, page 71, 2012). For dermally applied products these include: (a) Children: Shampoo and body lotion; (b) Adults: Hair care, bathing and showering, skin care, make-up (minus lipstick at 25% of the reported use for these products), and deodorant (using the highest value among these products and assuming that an individual will likely use only one type of deodorant).

[10] Children are assumed to use one-third of the amount of shampoo and body lotion that adults use.

[11] Reference: Stauber, J.L, et al., 1994, "Percutaneous absorption of inorganic lead compounds." Sci. Total Environ. **145**: 55-70.

[12] Bioavailability is assumed to be 100% in the absence of more definitive information.

[13] Calculation: PTTI ÷ (Exposure x Percutaneous Absorption). For example, for children: 6 ÷ (2.65 x .003) = ~750

[14] Children are rare to infrequent users of lipsticks.

[15] See Footnote # 3 above:FDA (1984) and as discussed in the "ICCR Traces Work Group: Discussion Paper for Lead The 75 % or (0.75) factor is appropriate for lipstick exposure.

[16] Literature references and discussions among the experts in the ICCR Traces Workgroup support the use of 70% bioavailability as the value commonly preferred for such calculations.

[17] Calculation: PTTI ÷ (Exposure x Amt Ingested x Bioavailability). For adults: 75 ÷ (0.057 x 0.75 x 0.70) = ~ 2500 ppm

[18] Calculation example: 25 ug Pb/day ÷ ((15.03 x .003) + (0.057 x 0.75 x 0.70)) = ~ 333 ppm

Annex III - Exposure Calculations Using 10 and 20 ppm as Examples[19]

GROUP	PRODUCTS	PRODUCT EXPOSURE (SCCS Dec 2012)	LEAD EXPOSURE assuming all products contain 10 ppm lead	LEAD EXPOSURE assuming all products contain 20 ppm lead
Children	Shampoo and body lotion	2.65 g/day	0.080 ug/day or 1.3 % of the PTTI[20]	0.16 ug/day or 2.7 % of the PTTI
Adults	Hair care, bathing and showering, skin care, make-up, and deodorant	15.03 g/day	0.45 ug/day	0.90 ug/day
	Lipstick	0.057 g/day	0.30 ug/day	0.60 ug/day
	TOTAL for Adults		0.75 ug/day or 1.0 – 3.0 % of the PTTI[21]	1.50 ug/day or 2.0 – 6.0 % of the PTTI

Calculations:

A. YOUNG CHILDREN

Dermal exposure to lead through use of cosmetics

(1) Products: shampoo and body lotion are the likely cosmetic products used by this age group. The SCCS reference contains values for adults. Arbitrarily, calculations below assume that young children might use one-third of what an adult might use.

Shampoo: 0.11 g/day daily exposure for adults or 0.037 g/day for young children

Body lotion: 7.82 g/day daily exposure for adults or 2.61 g/day for young children.

[19] Reference: European Commission, Directorate-General for Health and Consumers, (2012) Scientific Committee on Consumer Safety (SCCS), "The SCCS's Notes of Guidance for the Testing of Cosmetic Substances and Their Safety Evaluation", 8th revision, 11 December 2012. (See Table 3 on page 71)

[20] PTTI for children = 6 ug/day

[21] Range given for adults (PTTI = 75 ug/day) and Pregnant and Lactating Women (PTTI = 25 ug/day)

Total = ~ 2.65 g/day.

(2) Assuming that, (a) percutaneous absorption of lead is 0.3%, (b) 100% of the absorbed lead is bioavailable, and (c) all shampoos and body lotions contain 20 ppm lead:

2.65 g/day x 0.003 x 20 ug Pb/g = ~ 0.16 ug Pb/day

This is 2.7% of FDA's PTTI of 6 ug Pb/day.

B. ADULTS

A. Dermal exposure to lead through use of cosmetics

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(1) Products: Hair care, bathing & showering, skin care, make-up and nail care, and deodorant = 15.03 g/day.

(2) Assuming that, (a) the percutaneous absorption of lead is 0.3%, (b) 100% of the absorbed lead is bioavailable, and (c) each of the named products above contains 20 ppm lead, and (d) all products used are used daily

15.03 g/day x 0.003 x 20 ug Pb/g = 0.90 ug Pb/day

B. Oral Exposure to Lead through use of lipstick

(1) Lipstick products: The 2012 SCCS guidance estimates a daily lipstick exposure of 0.057 g/day. A 0.75 factor is applied for ingestion of lipstick. (See footnotes # 3 and 14) Accordingly, exposure to lipstick is calculated:

0.057 x 0.75 = 0.043 g/day.

(2) Assuming that, (a) 70% of the absorbed lead is bioavailable, and (b) all lipstick products contain 20 ppm lead:

0.043 g/day x 0.70 x 20 ug Pb/g = 0.60 ug Pb/day

C. Total exposure to lead from dermally applied cosmetics and lipstick (exclusions noted):

0.90 ug Pb/day + 0.60 ug Pb/day = 1.50 ug Pb/day

This is approximately 6.0 % of the FDA's PTTI of 25 ug Pb/day for pregnant and lactating women.

This is approximately 3.0 % of the FDA's PTTI of 75 ug Pb/day for adult women.**Annex IV – Steps for Reducing Lead Content in Cosmetic Products (excluding products used in the oral cavity)**

Analytical data available for lead content in cosmetic products finds that, while the majority of products contain lead at levels equal to or below 10 ppm, a very small percentage of foundations and eye products may contain lead at levels above 20 ppm.

In order to align all products to a uniform level of lead, all responsible persons (for example manufacturers, packers and importers) may need to take steps that impact on their current processes for control of raw material and the manufacturing processes. Because of the complexity of manufacturing (including labeling), and raw material sourcing and control, 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 due to the many steps necessary for product development, raw material selection and control, manufacturing and labeling (if reformulation is necessary).

Considering these factors, steps that may be necessary to achieve aligned level for lead 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 on the basis of "full heavy metal content". This will alert them to specify or to support the "full heavy metal content" in the raw material, ie, after complete digestion of samples. Any change in the attributes of a raw material requires assessment and possible modification of these elements.

- 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 total trace lead (as compared to extractable lead) 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 can significantly impact on established procedures.

- 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. Because of 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.

The members of the Traces WG agree that it is desirable to reduce the trace levels of lead in finished products with respect to the “As Low As Reasonably Achievable” (ALARA) principle. Importantly, this principle also takes into account what is technically feasible.

Implementation of time frames to achieve consistency of trace lead levels in cosmetics should take into account the practical impact of these changes and the time necessary for suppliers and manufacturers to adjust to current procedures. As a practical matter, the impact on the industry should be minimal because it appears that, for the majority of products, a level of 10 ppm or less is already technically achievable and will not require any adjustments to existing controls.