Exposure Assessment Methodology

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REVISION HISTORY

REVISION DATE	SECTION(S)	TYPE OF CHANGE	AUTHORIZED BY
September 22, 2017	Initial Release		S. Klosterhaus
March 2018	3.1.1	Added interpretation of how to assess exposure to vanadium or other non-lead, non-nickel toxic metals that are part of the alloy crystallites in a true alloy such as steel.	S. Klosterhaus
March 2018	3.2.1	Clarified the documentation needed for final manufacturing sites that are not visited (including those for MHCs).	S. Klosterhaus
March 2018	3.2.3a(i)	Clarified scope of the material "bound to or encapsulated by the material matrix" to include metals within metal alloys when a part of the alloy crystallites.	S. Klosterhaus
March 2018	3.2.3b(iv)	Clarified assumption of environmental exposure during use to include cases where there is aquatic toxicity but no GREEN ratings for Persistence and Bioaccumulation.	S. Klosterhaus
March 2018	3.2.4a(iii)	Clarified scope of bound materials in a matrix to include metals.	S. Klosterhaus
September 2018	3.2.1(i) and Appendix 1	Added options for assessing effluent.	S. Klosterhaus
September 2018	3.2.3	Clarified that the use phase questions can be applied to intermediate products in some cases.	S. Klosterhaus
September 2018	3.2.3 and Appendix 2	Added requirements for verifying that exposure to dermal sensitizers is not plausible during professional use.	S. Klosterhaus
October 2020	3.1.1	Added a footnote clarifying how to interpret the "others" category that is sometimes included on alloy spec sheets.	S. Klosterhaus

REVISION DATE	SECTION(S)	TYPE OF CHANGE	AUTHORIZED BY
October 2020	3.1.2, step 1b, c.ii	Deleted "and boiling point is > 400ºC" and added a footnote clarifying that modeled data may be used for vapor pressure determination.	S. Klosterhaus
October 2020	3.2.2 and Appendix 2	Added section to clarify exposure considerations for subsequent manufacturing steps that were previously addressed in other sections.	S. Klosterhaus
October 2020	3.2.3	Clarified the processes and products this section is applicable to. Clarified exposure considerations for professional installation, application, use and/or maintenance that were previously addressed in the use stage section.	S. Klosterhaus
October 2020	3.2.3b and Appendix 2	Clarified the exception for intermediate and other professional use products, which allows for the inclusion of a disclaimer on the certificate regarding issues with sensitization or corrosion/irritation (not previously addressed) when evidence of training on proper handling of product and use of PPE is provided.	S. Klosterhaus
October 2020	3.2.4 a.i	Added quartz in bulk form as another example of substances that may be considered bound in a material matrix. This is also now noted in section 3.2.1.	S. Klosterhaus
October 2020	3.2.4 iv	Clarified the categories of products that must be considered to be released to the environment during use.	S. Klosterhaus
October 2020	3.2.5	Clarified which end of use scenarios must be considered for long use phase products.	S. Klosterhaus

REVISION DATE	SECTION(S)	TYPE OF CHANGE	AUTHORIZED BY
November 2021	3.1.1 Step 1A	Added rule for PURPLE hazard rating for the combined PB hazard flag	S. Klosterhaus
November 2021	3.2.1 Final Manufacture	Updated to ensure that the fate of individual chemicals potentially entering the effluent are addressed appropriately (volatilization, adsorbance to sludge, and ultimate fate are now considered).	S. Klosterhaus
November 2021	Appendix 1	Limits to assessment of effluent and air have been updated and sections have been added for the assessment of effluent using the mixture rules and the Predicted No-Effect Concentration (PNEC).	S. Klosterhaus
February 2022	3.1.1 Step 1A	Corrected exposure assumption for the Combined Persistence and Bioaccumulation Hazard Flag to include PURPLE or RED flags unless closed loop recycling is taking back 80% or more of the product.	S. Klosterhaus
February 2022	Appendix 2 A	Added verification requirements for fully closed and sealed avoidance systems or processes.	S. Klosterhaus
February 2022	Appendix 2 B	Clarified training requirements for professional users regarding safe handling of product to avoid contact or repeated contact for corrosion/irritation and sensitization, respectively.	S. Klosterhaus
January 2024	Appendices 2 A and 2B	Performed formatting and other edits to make the appendices consistent with the rest of the document.	S. Klosterhaus
January 2024	Appendices 2 A and 2B	Added guidance to perform the literature search regarding the effectiveness of PPE.	S. Klosterhaus

REVISION DATE	SECTION(S)	TYPE OF CHANGE	AUTHORIZED BY
January 2024	Appendix 2 B	Added a compliance pathway for regions where regulations cover hazard communication and training for personal protective equipment (PPE).	S. Klosterhaus

1 DOCUMENT OVERVIEW

1.1 PURPOSE AND CONTENT

The Cradle to Cradle Certified® exposure assessment method is briefly described in the Cradle to Cradle Certified Material Health Assessment Methodology document. The purpose of this document is to clarify and further define how to complete an exposure assessment.

An exposure assessment is completed after hazard ratings have been assigned to individual endpoints. Once an exposure assessment is complete, risk flags, abc-x single chemical risk ratings, and ABC-X material assessment ratings may be assigned. The process for assigning hazard ratings, risk flags, abc-x single chemical risk ratings, and ABC-X material assessments are further described in the Cradle to Cradle Certified Material Health Assessment Methodology.

1.2 SUPPORTING DOCUMENTS

The following documents are to be used in conjunction with this document:

- Cradle to Cradle Certified® Product Standard
- Cradle to Cradle Certified® Product Standard User Guidance
- Cradle to Cradle Certified® Material Health Assessment Methodology
- Any applicable Cradle to Cradle Certified® standard documents and methodology documents posted on the C2CPII website.

2 EXPOSURE ASSESSMENT OVERVIEW

2.1 A QUALITATIVE, NOT QUANTITATIVE APPROACH

Exposure to a chemical substance in conjunction with its inherent hazard properties will determine its effect on target organisms or target organs/tissues. In the Cradle to Cradle Certified Material Health Assessment and Exposure Assessment Methodologies, the likelihood of detrimental effects, or risk, is considered to be a function of intrinsic hazard and exposure. The Cradle to Cradle methodology differs from traditional exposure and risk assessment in that no attempt is made to quantify the amount of exposure that occurs.

2.2 SUMMARY OF METHODOLOGY

The exposure assessment for an individual chemical begins when the chemical has been associated with a particular material and product, and the chemical hazard profile has been completed. At this point, each hazard endpoint will have been assigned a GREEN, YELLOW, RED or GREY hazard rating. An exposure assessment is then completed separately for individual hazard endpoints.

An exposure assessment is primarily undertaken when RED or GREY hazard ratings for one or more endpoints have been assigned. Exposure assessment is optional in the case of a YELLOW or GREEN hazard rating. Therefore, for the remainder of these instructions it is assumed that only RED and GREY hazard ratings are under consideration.

If exposure is unlikely to occur, one or more RED or GREY hazard ratings can be assigned YELLOW risk flags. In order to assign a YELLOW risk flag to an endpoint with a RED or GREY hazard rating, it must be determined that relevant exposure is unlikely in all use cycle stages[1], beginning with the final manufacturing stage. If there is uncertainty regarding whether or not exposure will occur, a precautionary approach is applied and exposure is assumed to occur.

Step 1 of the method addresses cases where exposure assessments are not required, either due to certain exceptions to the rules or because data gaps do not affect the single chemical risk rating. Step 2 explains how to incorporate exposure considerations when required. If, after Step 1 is complete, only YELLOW and GREEN hazard ratings remain for the chemical under consideration, then a single chemical risk rating of 'c' may be assigned and the exposure assessment is complete (i.e. it is not necessary to conduct Step 2).

It usually will not be necessary to go through every step of the exposure assessment process for each RED or GREY endpoint, depending on the specific chemical's hazard profile, the material it is in, and product

[1] All use cycle stages = final manufacturing, installation, use, and end of use (e.g., recycling, incineration, back yard burning and/or landfill). Commonly known as life-cycle stages.

context. This is because a single RED risk flag leads to an x single chemical risk rating, thus obviating the need for further assessment. If a definitive abc-x rating can be derived for a substance following any subset of the rules below for any number of endpoints, the remainder of the rules and/or endpoints need not be evaluated. In addition, the Cradle to Cradle Mixture Rules should be consulted as they may influence whether or not an exposure assessment is required.

2.3 SPECIAL CONSIDERATIONS: TOXICITY TESTING OF MIXTURES

In some cases, toxicity testing may have been performed on an entire homogeneous material or formulation. If such testing makes it possible to assign a GREEN or YELLOW hazard rating to one or more endpoints for a homogeneous material, this may be used in place of toxicity data and associated hazard ratings for individual chemicals within the material or formulation. In this case an exposure assessment would not be required for the relevant endpoints of the individual chemicals. Instead, if relevant RED hazard ratings are identified for the homogeneous material, an exposure assessment should be undertaken for the homogeneous material. Tests that are sometimes available for homogeneous materials or formulations are those relevant to the *Sensitization of Skin and Airways*, aquatic toxicity (*Fish Toxicity, Daphnia Toxicity* and *Algae Toxicity*), and acute toxicity (*Oral Toxicity*) endpoints.

2.4 MAINTAINING CONSISTENCY

For the purposes of Cradle to Cradle certification and the Cradle to Cradle Material Health Certificate Program, exposure assessments are conducted by Cradle to Cradle Products Innovation Institute (C2CPII) accredited material health assessment bodies, who have expertise in the areas of chemistry and toxicology. Assessors are required to follow the methodology described in this document when carrying out an exposure assessment to ensure consistency among Material Health assessments.

This methodology aligns with current Cradle to Cradle Certified exposure assessment practices and covers common chemicals, materials, and product types. However, new and/or uncommon chemicals and materials, or unique exposure scenarios, may occasionally need to be assessed. In addition, the availability of new information, data, and/or techniques may result in the need for altered methods. Therefore, assessors must use their expert knowledge and critical thinking when completing each exposure assessment to ensure that a precautionary approach is always taken. In the case that an assessor finds that the method below would result in a less than precautionary outcome, or believes that these rules do not result in the correct assessment rating, that assessor is required to notify C2CPII so that the best approach can be determined and consistency can be maintained. Assessors may use alternative exposure assessment methods only upon discussion with and pre-approval from C2CPII.

3 EXPOSURE ASSESSMENT METHODOLOGY

3.1 STEP 1: IDENTIFY ENDPOINTS AND SPECIFIC ROUTES OF EXPOSURE WITHIN ENDPOINTS THAT DO NOT REQUIRE AN EXPOSURE ASSESSMENT

The Outcome of Step 1:

- If Step 1A requires that a RED risk flag and x single chemical risk rating be assigned to any endpoint, the homogeneous material will be X assessed.
- If Step 1A does not require that a RED risk flag be assigned to any endpoint, and any GREY hazard ratings are due to data gaps that do not affect the single chemical risk rating as described in Steps 1A and 2, then the single chemical risk rating will be 'c' and the homogeneous material will be C assessed.
- For all other endpoints that are still assigned either RED or GREY hazard ratings after Step 1 is complete, follow the methodology outlined in Step 2.

3.1.1 Step 1A: Exclude endpoints for which there are exceptions to the rules

1. Chemicals of regulatory concern,[2] are always assigned risk flags equal to their hazard ratings. Therefore, an exposure assessment is not necessary in these cases. The relevant regulatory conditions including thresholds apply. An exposure assessment may be completed when these substances are used in non-regulated applications or below the relevant threshold.[3]

2. Substances with a RED or PURPLE hazard rating for *Persistence* and *Bioaccumulation* as well as a RED hazard rating for toxicity of any type (i.e. any endpoint) will always be x assessed. This is because persistence and bioaccumulation enhance the exposure potential. For such substances, it is assumed that exposure will eventually occur. (However, see the special conditions for metals listed in point #5 below which take precedence.)

[2] Per Standard Version 3.1, a chemical of regulatory concern is defined as any chemical currently restricted under REACH Annex XVII (see the conditions listed by REACH; e.g. at the time of writing this document, all category 1 & 2 CMRs were of "regulatory concern" when used in "mixtures intended for supply to the general public" i.e. formulated consumer products) on the REACH candidate list for Substances of Very High Concern (SVHC), or on the POPs list of the Stockholm Convention. This set of lists is subject to change. The most current version of the lists or regulations is to be used at the time of the Material Health assessment is being conducted.

[3] Rationale: This approach is taken for several reasons: Prior to inclusion in the regulatory lists indicated, some consideration of exposure and risk has already occurred. In addition, this approach will ensure that chemicals or materials that cannot be sold into the EU will not be Cradle to Cradle C or B-assessed or allowed in Gold certified products. The approach also ensures that manufacturers participating in the program are made aware of the chemicals of regulatory concern within their products and are encouraged to work on phasing these chemicals out.

3. Substances with a PURPLE or RED hazard rating for the combined Persistence and Bioaccumulation (PB) hazard flag (see Section 3.3.16 and Table 21 of the Material Health Assessment Methodology, October 2021 Revision) are always x assessed, unless a closed loop recycling system is taking back 80% or more of the product and exposure is not likely during the manufacturing and use phases. If the combined PB hazard flag is GREY, the usual steps in the Exposure Assessment Methodology apply. In cases where exposure is assumed, the combined PB risk flag is the same as the combined PB hazard flag.

4. The exposure assessment does not need to be completed for the following endpoints when they have been assigned GREY hazard ratings: *Carcinogenicity*, *Endocrine Disruption*, *Neurotoxicity* and *Terrestrial Toxicity*. This is because a GREY hazard rating for these endpoints does not affect the single chemical risk rating.

5. There are several additional cases for certain material types where GREY hazard ratings do not affect the single chemical risk rating. These materials are covered by specific guidelines. Currently they include pigments, which are assessed according to the Colorants Assessment Methodology, and certain biological and geological materials, as outlined in the Biological Materials Assessment Methodology and the Geological Materials Assessment Methodology. Please see the most recent versions of those documents for further information.

6. If a RED hazard rating has been assigned to the *Climatic Relevance*, *Organohalogen*s,[4] or *Toxic Metals* endpoints, the chemical will be x assessed, unless one of the exceptions for *Toxic Metals* listed below applies, given the material/product context. In these cases, all endpoints with RED or GREY hazard ratings related to the metal in question may be assigned a YELLOW risk flag and the material may be C assessed (assuming no other RED or GREY risk flags are present for other chemicals in the material) as long as the answers to the final manufacturing stage questions in Step 2, when relevant to handling of the material in question, are YES.

Cases for which a RED hazard rating for Toxic Metals *may not lead to an x assessment:*

a. The toxic metal is used in a colorant and it is in a stable crystalline form exhibiting low toxicity (e.g. spinel and rutile forms). See the Colorants Assessment Methodology for further information.

b. The toxic metal is fused within glass. The metal is not present at ≥ 100 ppm in the crystalline form (i.e. it is not in the form of a salt, for example a metal oxide or metal sulfate) but is present only in the ionic form and is bound within the silicate glass structure.

[4] Note: Organohalogens and the toxic metals lead, cadmium, mercury and hexavalent chromium are subject to review at any level. However, a material will always be X assessed only if these substances are present ≥ 100 ppm. Lower thresholds apply for these Toxic Metals in biological nutrients (2ppm Cd, 90ppm Pb, 100 ppm Cr+6, 1ppm Hg).

Leaching tests are required to demonstrate non-detectable migration unless studies clearly support lack of migration and subsequent exposure concerns for the product type under consideration (e.g. testing would be required for leaded glass in food contact).

c. The toxic metal is lead contaminating a metal alloy (e.g. A380) due to use of recycled content. In this case the thresholds for lead are aligned with the RoHS thresholds when answers to Step 2 use stage questions 3.2.4a and/or b (Oral) are **YES**. The RoHS threshold for lead in aluminum is 0.4% at time of publication. This threshold may be lowered to 0.1% in the future. The RoHS threshold for lead in steel is 0.35%. This threshold will be applied to all metal alloys other than aluminum. Therefore, at the time of publication, if the conditions within point c are met, lead may be present in aluminum at ≤ 0.4% and in other metals at ≤ 0.35% and the metal may be C assessed.[5] If lead is intentionally added to improve machinability of aluminum, steel, or brass, the 0.01% (100 ppm) threshold applies and the metal must be X assessed (but also see point f below). Note that standard composition information for some metal alloys does not always list percentage lead content even though lead may be present. If lead is not listed, the assessor may need to communicate with suppliers and/or obtain information from the relevant metal industry group or producer regarding typical lead content for the alloy under consideration to ensure that full material disclosure has been obtained prior to assigning a C assessment[6].

d. The toxic metal is nickel within a steel alloy and it does not come into contact with human skin as a part of the product's intended use. If it is intended to come into prolonged or repeated contact with human skin during the product's use, it is given a RED risk flag for *Sensitization of Skin and Airways* and the *Toxic Metals* endpoints and the steel will be X assessed, unless the nickel release rate is shown to be below 0.5 µg/cm^2/week or below 0.2 µg/cm2/week for parts of products inserted into pierced ears and other pierced parts of the human body, or in direct contact with skin as determined via leaching tests on the material in accordance with the standards adopted by the European Committee for Standardization.[7]

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[5] RoHS Exemption FAQ, The Aluminum Association (accessed August 11, 2020). The lead in aluminum threshold for children's products in the US is 300 ppm (100 ppm for other materials used in children's products). See: Petition Requesting Exception from the Lead Content Limits, 2011 AND Technological Feasibility of 100 ppm for Lead Content, 2011, AND Final Decision. EU Directive relevant to children's products/toys that may be mouthed sets limit at 0.05% lead by weight: Commission Regulation (EU) 2015/628.

[6] In cases where lead or other toxic metals are not explicitly listed on alloy composition data sheets but could be part of "others" present at up to 0.05% each (a common category on ASTM specification sheets), the possible presence of lead or other toxic metals does not have to be considered as part of the assessment. However, if lead or other toxic metals are explicitly listed at ≥ 0.01%, it must be assumed that they have been added intentionally unless supplier(s) of the material(s) confirm otherwise.

[7] As of the time of writing the applicable test methods are EN 1811, and if nickel-containing alloy is coated additionally EN 12472. EN 16128 is to be used for glasses. Any future applicable test methods that may be released by the European Committee for Standardization for nickel leaching tests are also to be used.

e. The toxic metal is vanadium in a steel alloy or a different non-lead, non-nickel, toxic metal part of the alloy crystallites in a true alloy[8] (needs to be demonstrated by the assessor) and exposure is not plausible during the final manufacturing, installation, use, or end of use phases.[7] In other words, in this case, the full exposure assessment method must be applied. However, the question relevant to the incineration scenario for end of use is not required unless it is needed in order to represent at least 80% of product sold. If recycling is one of the relevant end of use scenarios, then it must still be demonstrated through a literature search that exposure during recycling operations is not plausible. Sufficient background information must be provided to support use of this exception. Also, see the exceptions specific to lead and nickel within metals, which include additional stipulations and take precedence.

f. Note that theoretically there is also the potential for materials containing toxic metals to be C assessed in the case that a recycling system under the control of the manufacturer is fully functioning, taking back 80% or more of products sold, and exposure is unlikely in the other use cycle stages based on the assessment process below. However, a situation such as this has not yet been identified.

3.1.2 Step 1B: Exclude endpoints and specific routes of exposure within endpoints based on physico-chemical properties

1. Data gaps are to be ignored for any route-specific endpoint, or individual routes of exposure within endpoints, that are deemed scientifically unjustified (i.e. exposure is unlikely or of low concern) based on the physico-chemical properties listed below.[9] However, if there are data indicating a hazard through a given route of exposure, it must be considered and the exposure assessment conducted, even if that route of exposure could be excluded based on these properties.

The following is a list of default situations by exposure route in which data gaps are to be ignored because exposure is unlikely or of low concern. Consider the temperature thresholds below in the context of the temperatures expected to occur during all use cycle stages including likely unintended use, cutting of materials during installation, etc. to ensure unlikely exposure. If extreme conditions are expected to occur, it may be necessary to alter these default assumptions (for example some home ovens can reach 500°F/260°C).

[8] **Definition of true alloy:** Substances present in the alloy are integral parts of the alloy (i.e. part of the alloy crystallites as opposed to being present between the crystallites). Note: Lead in aluminum or steel is present between the crystallites.

[9] Note: This point is tied both to whether or not toxicity data need to be collected for specific endpoints, as well as to whether or not certain routes of exposure need to be considered when completing Step 2. For example, *Mutagenicity* and *Endocrine Disruption* tests typically do not provide information regarding route of exposure. For this reason, it will be useful to determine if some routes are of low concern prior to completing Step 2. On the other hand, if inhalation exposure is deemed of low concern due to the boiling point, data would not be required for the *Inhalation Toxicity* endpoint when completing the chemical profile (i.e. a GREY hazard rating would not affect the overall abc-x rating).

a. Oral exposure is of low concern when consumption or absorption are unlikely.

- **i.** Consumption is unlikely when the chemical is highly volatile (defined as boiling point less than 0°C).[10]
- **ii.** Absorption is unlikely when molecular weight is greater than 1000 g/mol[11] and the molecule is known not to undergo hydrolysis or cleave under acidic conditions (e.g. starch has a molecular weight much greater than 1000 but is absorbed once ingested).
- **iii.** Absorption is unlikely when the substance meets at least three of the following conditions[12]:
    1. Molecular weight is greater than 500 g/mol
    2. The octanol-water partition coefficient (log K_{ow}) is greater than 5
    3. The substance has more than 5 hydrogen bond donors (defined as the total number of nitrogen-hydrogen and oxygen-hydrogen bonds)
    4. The substance has more than 10 hydrogen bond acceptors (defined as all nitrogen and oxygen atoms)

b. Dermal exposure (i.e. dermal absorption) is of low concern when:

- **i.** Molecular weight is greater than 1000 g/mol[13, 14, 15] OR;
- **ii.** Molecular weight is greater than 500 g/mol AND the log K_{ow} is greater than 4.[16]

c. Inhalation exposure to volatiles is of low concern when:

- **i.** Boiling point is greater than 240°C,[17] OR;

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[10] Technical Overview of Volatile Organic Compounds, U.S. Environmental Protection Agency. (accessed May 17, 2017).

[11] Hazardous Substances in Plastic Materials, Danish Technological Institute, 2013.

[12] Note: This is Lipinski's rule of 5. There are many references available on this topic.

[13] Draft Guidance Notes for the Estimation of Dermal Absorption values, OECD, 2008. and update: Guidance Notes on Dermal Absorption, OECD 2011.

[14] "Generally the smaller the molecule the more easily it may be absorbed. Molecular weights below 500 are favorable for absorption; molecular weights above 1000 do not favor absorption." Source: Guidance for Human Health Risk Assessment (Biocides), ECHA, 2013.

[15] This reference states that "...a rule of thumb on dermal absorption used in the EPA/OPPT New Chemical Program assumes 10% dermal absorption (multiply exposure value by 0.1) for chemicals with MW > 500 AND log Kow < -1 or > 4 and assume 100% dermal absorption for all other chemicals." Interpretive Assistance Document for Assessment of Discrete Organic Chemicals, Sustainable Futures Summary Assessment, US EPA, June 2013 (accessed May 17, 2017)

[16] per conversations with the American Chemistry Council (ACC) referencing EPA Sustainable Futures, OECD, and ECHA. Also, based on unpublished work by the ACC that compared these properties between two groups of substances (one group of high concern and another group of low concern).

[17] Technical Overview of Volatile Organic Compounds, US EPA. (accessed May 17, 2017)

ii. Vapor pressure is less than 10^{-6} mm Hg.[18]

d. Inhalation exposure to particulates and aerosols is of low concern when the aerodynamic diameter is greater than 100 µm.[19]

e. Aquatic toxicity is of low concern when solubility is less than 0.001 mg/l.[20] The combined aquatic risk flag and associated instructions further define situations in which exposure to the aquatic environment is of low concern. At higher solubilities, a comparison between the solubility level and toxic concentrations can be made, as explained in the Aquatic Toxicity section of the Material Health Assessment Methodology (see paragraph on *Poorly Soluble Substances*).

3.2 STEP 2: DETERMINE IF PROCESSES AND PRODUCT ARE DESIGNED TO PREVENT EXPOSURE

How to apply Step 2:

- If considering a RED or GREY hazard for an environmental health (EH) endpoint, then the questions below marked for EH are to be asked. If considering a RED or GREY hazard for a human health (HH) endpoint, then the questions marked for both HH and EH are to be asked.
- Only those routes of exposure that are possibly relevant to the endpoint in question (as determined in Step 1) need to be considered. In the case that some endpoints and routes of exposure within endpoints were not excluded (i.e. determined to be unlikely/of low concern) within Step 1, then the following must be assumed to be possibly relevant when beginning Step 2: Oral exposure, dermal exposure, exposure via inhalation, and exposure to the environment (i.e. release to air/water/soil). These routes of exposure are possibly relevant to all endpoints except where the endpoint, by definition, applies only to certain exposure routes (e.g. for Oral Toxicity the oral and environmental exposure routes are to be considered possibly relevant when beginning Step 2).
- Note that in some cases where the assessment process below would result in a RED risk flag, it would be possible for the assessor and applicant to follow up by having specific tests completed to show that the chemical of concern is removed, degraded, or not migrating, leaching, or washing out, etc. above thresholds of concern (e.g. if it is shown that a textile produced using a sensitizing dye is not in itself sensitizing.[21]) However, specific testing methods and thresholds that would be

[18] Interpretive Assistance Document for Sustainable Futures Summary Assessments, Assessment of Discrete Organic Chemicals, US EPA (2013). Note: The value in point c.ii may be below what can be measured analytically. US EPA thresholds assume use of modeled data. If analytical data are not available, refer to modeled data for making this determination (e.g. per EpiSuite).

[19] Threshold Limit Values for Chemical Substances and Physical Agents, ACGIH, 1993.

[20] Flame Retardants in Printed Circuit Boards, US EPA, August 2015 and references therein.

[21] Refer to the Cradle to Cradle Colorants (Textile Dyestuffs and Pigments) Assessment Methodology.

required and acceptable for Cradle to Cradle Certified have not yet been developed. Appropriate tests would need to be approved by C2CPII at which point they would be added to this document. This note has been inserted within the methodology as a holding place and to indicate that this approach will be further developed in the future.

The outcome of Step 2:

- In the case of a RED risk flag resulting from a RED risk in one or more use cycle stages, the single chemical risk rating will be 'x' and the homogeneous material will be X assessed. In the case of a GREY risk flag, the single chemical risk rating will depend on whether or not there are any RED risk flags for other endpoints. If not, the rating will be GREY.
- In the case that exposure is unlikely in all use cycle stages, a YELLOW risk flag may be assigned to the endpoint in question. When all endpoints for the chemical in question receive YELLOW or GREEN risk flags, the single chemical risk rating will be 'c' or 'b', respectively.

3.2.1 Final Manufacture

The final manufacturing stage includes the processes defined by the Cradle to Cradle Certified Methodology for Applying the Final Manufacturing Stage Requirements. Note that the 'final' manufacturing stage is relative to the applicant's product that is being assessed. The product may be a consumer product or a business to business product – including intermediate products and raw materials for which subsequent manufacturing steps will occur.

A site visit is required at the final manufacturing stage facility or facilities to verify answers to the questions below. For any sites that are not visited, and in the case of Version 3.1 Material Health Certificate applications, the assessor must verify answers to the questions below by reviewing documentation provided by the applicant's Environmental, and Safety personnel (e.g. EH&S management system, processes and procedures).

The answer must be **YES** to **one** of the following (a-b) in order to assign a YELLOW risk flag for this stage (unless considering an endpoint that may be GREY without affecting the single chemical risk rating as mentioned in Step 1). If the answers are all **NO** or unsure, assign a RED or GREY risk flag as appropriate. If a RED or GREY risk flag is assigned for this stage, the exposure assessment is complete (i.e. there is no need to continue to the questions for subsequent manufacturing, installation/maintenance, use, or end-of use).

a. **HH & EH: Is the chemical reacted into a material prior to the final manufacturing stage such that exposure during final manufacturing is not likely to occur?** The answer to this question will be **YES**, when the chemical is:
    i. Bound to or encapsulated by the material matrix (e.g. titanium dioxide and carbon black as polymer fillers/pigments or within liquids or gels (e.g. paint), other inorganic pigments within polymers, polymer crosslinkers, and colorants fused within a glass matrix, metals

within metal alloys when part of the alloy crystallites [also see exceptions for Toxic Metals in section 3.1.1], and quartz (SiO_4) in bulk form or bound within a polymer matrix.) This includes the molecules of the matrix itself, as in the case of solid plastics and other substances with molecules of diameter greater than 950 µm.[22]

ii. A polymer additive with molecular weight greater than 1000 g/mol. For example, flame retardants and plasticizers with molecular weights greater than 1000 may be considered bound by the polymer. Substances with low molecular weights including residual monomers, some oligomers (e.g. styrene trimers and dimers), some additive flame retardants, residual solvents, and substances that are known to degrade to substances with molecular weights less than 1000 once incorporated into a polymer cannot be assumed to remain within the polymer matrix.

Note: Certain conditions (e.g. temperature, pH) and processes (e.g. sawing, grinding) may affect whether or not a substance remains bound within a material. The questions above must be answered within the range of conditions expected to occur at final manufacturing locations.

b. Is exposure via the relevant routes sufficiently controlled during final manufacturing? The answers must be **YES** to all questions below pertaining to all relevant exposure route(s) in order to assign a YELLOW risk flag based on question b.

i. HH: Are effective administrative or engineering controls[23] in place and/or is sufficient personal protective equipment (PPE) in use? Assessor to consider EU & US OSHA requirements for the relevant industry, OSHA compliance, and Safety Data Sheet (SDS) indications when determining what, where, and how PPE should be used. If the manufacturer is located in a country with well-developed and enforced worker health and safety regulations[24] and the manufacturer has not had any OSHA violations or similar (depending on region) in the last two years relevant to chemical toxicity, then it may be assumed, at the assessor's discretion and upon consideration during the site visit, that sufficient PPE is in use. If insufficient controls or PPE are used, assign a risk flag equal to the hazard rating (i.e. if the hazard rating is RED or GREY, the risk flag will also be RED or GREY).

ii. HH & EH: **Are sufficient controls in place to keep the chemical out of environmental media (air/water/soil)?** Assessor to consider Best Available Techniques (BATs)[25] for the industry in question and adherence to these techniques in determining if sufficient controls are in place. However, release to the environment and subsequent human and environmental

[22] Targeted Risk Assessment, Technical Report No. 93., ECETOC, December 2004. See page 109.

[23] Definition of administrative and engineering controls per the Center for Disease Control.

[24] Countries currently assumed to have well-developed and enforced worker health and safety regulations are countries within the EU, Switzerland, United Kingdom, United States, Canada and Japan. Note: This list may be extended in the future.

[25] Link to Best Available Techniques documents (EU).

exposure (e.g. via ground or surface water) is deemed likely in cases where the effluent used in product manufacture leaves the facility (i.e. process water is not kept flowing in a closed loop) unless one or more of the following is true:

1. Testing using appropriate analytical methods and detection levels for the contaminant in question has shown that the chemical with the RED or GREY hazard rating is:
    a. not present in effluent (i.e. it is below detection limits).[26] Exception: this method may not be used when objective limits are below the limits of quantification (applicable to priority substances for which objective limits have been set),
    b. a priority substance that is present in effluent below objective limits set for water bodies (see Appendix 1 for further information), or
    c. present in effluent at or below the incoming concentration (#3 applies only when contamination of incoming water is outside the applicant's control);
2. Water only comes into contact with the product at a point when the chemical with a RED or GREY hazard rating is unavailable for release (i.e. it is reacted into the material matrix as described above in question a.i-ii);
3. The chemical's hazard rating for *Persistence* is GREEN or, in the case of the aquatic toxicity endpoints (fish, daphnia, algae), the combined aquatic toxicity flag is YELLOW (i.e. Persistence and Bioaccumulation are both GREEN when the aquatic toxicity hazard rating and risk rating are RED or GREY). NOTE: If the chemical will be exposed to anaerobic conditions (i.e., anaerobic digestion or substances that are expected to end up in sediment), the hazard rating for Persistence may be GREEN in either anaerobic or aerobic environments (both are predicted by the US EPA's BIOWIN).
4. Process water is kept flowing in a fully closed loop. This is defined as a closed loop system that does not produce sludge-containing chemicals in scope and that is not periodically flushed, resulting in release of chemicals in scope with effluent.

If none of the above are true, a RED or GREY risk flag (as relevant) may be assigned for the Final Manufacturing Stage context (and no further assessment work or analytical testing is required[27]). Alternatively, the exposure assessment may continue as follows:

1. The fate of the chemical once it enters the effluent must be determined based on its physico-chemical properties.[28] At least some of the chemical is assumed to be present in each compartment (sludge, water, air) where the following are true:
    a. Present in sludge if:

[26] Note: Appropriate analytical methods and detection limits have not been defined yet for Cradle to Cradle Certified.

[27] Note: Although testing is not required when assessing product relevant effluent for the purposes of this proposal, testing is required per some of the other water stewardship proposals.

[28] US EPA, Interpretive Assistance Document for Assessment of Discrete Organic Chemicals, Sustainable Futures Summary Assessment, June 2013. https://www.epa.gov/sites/production/files/2015-05/documents/05-iad_discretes_june2013.pdf

i. The soil adsorption coefficient (log K_{oc}) is ≥ 1.5[29] and
ii. The substance is not highly volatile from water: Henry's Law constant < 10-1

b. Present in water if:

i. The soil adsorption coefficient (log K_{oc}) is < 4.5 and
ii. The substance is not highly volatile from water: Henry's Law constant < 10-1

c. Present in/released to air if:

i. Henry's law constant is > 10-5 (values above 10-5 are defined as moderately to very volatile from water)

Then, an assessment must be completed for each compartment that the chemical is expected to enter as follows:

2. If a portion of the chemical is expected to remain in the water (meets condition 1b above), a RED or grey risk flag must be assigned unless testing using appropriate analytical methods and detection levels for the contaminant in question has shown that the chemical with the RED or GREY hazard rating is not present in effluent (i.e., is below detection limits) OR is present below safe limits. This is described in the Effluent: Analytical Testing Methods & Limit Values section below.
3. If a portion of the chemical is expected to adsorb or adhere to the sludge (meets condition 1a above), then a RED or grey risk flag must be assigned unless the sludge, biosolids (dried and sanitized sludge), and/or digestate resulting from anaerobic digestion of the sludge (if such digestion occurs prior to disposal), are processed appropriately. This can be determined based on the following questions:
   a. If landfilled, answer the questions posed in the Landfill section of the Exposure Assessment Methodology. (NOTE: this will not allow for assigning a YELLOW risk flag to a RED or grey hazard rating because substances that are not contained within a material matrix are assumed to leach from the landfill eventually. Therefore, it must be assumed that hazardous chemicals in sludge will eventually leach from landfills. No distinction is made between a hazardous waste or conventional landfill.)
   b. If land applied or composted, answer the questions in the Compost section of the Exposure Assessment Methodology. (NOTE: this also will not allow for a YELLOW risk flag). Land application as a soil amendment is the most common end of use

[29] Estimates of log Koc are available in the US EPAs EpiSuite. Specifically, KOCWIN estimates Koc using the Molecular Connectivity Index (MCI) and a log Kow-based method. The MCI method is more robust and is preferred per https://www.epa.gov/sites/production/files/2015-05/documents/05.pdf

fate of biosolids and digestate in many locations unless identified as hazardous waste per regulatory definitions.

c. If incinerated, and the substance is not RED for the Toxic Metal endpoint and also is not an organohalogen, then a RED or grey hazard rating may be assigned a YELLOW risk flag.

d. If recycled in a process of nutrient recovery (e.g. the chemical is removed from sludge and reused at the manufacturer's facility), and appropriate PPE is in use as determined at the site visit, a RED or grey hazard rating may be assigned a YELLOW risk flag.

NOTE: Appropriate test methods and limits relevant to sludge are not available at this time. Therefore, testing of sludge to show that hazardous chemicals are present below detection (or safe) limits is not provided as an option. For example, In the US, biosolids only have to be tested for metals and pathogens. The amount that is land applied is also regulated because some metals typically remain in the material.[30] In the EU, limits on metals for land application are set by individual member countries.[31] However, "because many pollutants are unregulated and the hazards posed by them are indeterminable, some regional states have banned the use of sewage sludge as fertilizer".[32]

4. If a portion of the chemical is expected to volatilize (meets condition 1c above) from the water and be released to air, then a RED or GREY risk flag must be assigned unless testing using appropriate analytical methods and detection levels for the contaminant in question has shown that the chemical with the RED or GREY hazard rating is not present in the air exiting control equipment (i.e. is below detection limits) OR is present below certain limits. In some cases a GREY rating is allowed in this context. This is described in the Air: Analytical Testing Methods & Limit Values section below. The fate of solid waste, if any, resulting from treatment (e.g., scrubber wet sludge) must also be assessed per the section for sludge above.

3.2.2 Subsequent Manufacturing

This section is applicable to intermediate products that are or will be Cradle to Cradle Certified or have a Material Health Certificate. Examples of intermediate products are printing inks and industrial coatings.

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[30] US EPA, Title 40 Part 305.13

[31] http://ec.europa.eu/environment/waste/sludge/

[32] https://www.umweltbundesamt.de/en/topics/soil-agriculture/ecological-impact-of-farming/compost-sewage-sludge

The answer must be **YES** to **one** of the following (a-b) in order to assign a YELLOW risk flag for this stage (unless considering an endpoint that may be GREY without affecting the single chemical risk rating as mentioned in Step 1). If the answers are all **NO** or unsure, assign a RED or GREY risk flag as appropriate. If a RED or GREY risk flag is assigned for this stage, the exposure assessment is complete (i.e. there is no need to continue to the questions for professional installation, application, and maintenance, use, and end-of-use). Note: In addition to the questions below, see the Colorants Assessment Methodology for additional rules applicable specifically to dyestuffs that are Cradle to Cradle Certified or have a Material Health certificate and will be used subsequently in textile dying operations.

a. **HH & EH: Is the chemical reacted into a material prior to subsequent manufacturing such that exposure during subsequent manufacturing is not likely to occur?** See section 3.2.1 a.i-ii for sub-questions. Note that certain conditions (e.g. temperature, pH, etc.) and processes (e.g. sawing and grinding) may affect whether or not a substance remains bound within a material. This question must be answered within the range of conditions expected to occur at subsequent manufacturing locations.

b. **HH & EH: Is exposure via the relevant exposure routes sufficiently controlled during subsequent manufacturing[33]?** The answers must be **YES** to all questions below pertaining to all relevant exposure route(s) in order to assign a YELLOW risk flag based on question b. Note: Oral exposure may be assumed implausible during subsequent manufacturing.

    i. **HH: Will the chemical be unavailable for human contact to occur during subsequent manufacturing, such that PPE or administrative controls (e.g. personnel rotation) are not required?** For example, it is sequestered within fully closed and sealed containers and self-cleaning lines during transport and transfer, and at <u>all</u> subsequent manufacturing facilities. If **NO** or unsure, and if chemical has a RED or GREY hazard rating for *Sensitization of Skin and Airways and/or Skin, Eye, and Respiratory Corrosion/ Irritation* go to the next question below:

        1. **HH – Dermal and/or Inhalation (sensitization and irritation/corrosion): Are workers at all subsequent manufacturing facilities adequately trained regarding safe handling of the product and the use of appropriate PPE?** If PPE is necessary to avoid exposure during subsequent manufacturing, sufficient use of PPE may only be assumed if workers

[33] Note: For intermediate products It is assumed that it will not be possible to verify that exposure is sufficiently controlled at all subsequent manufacturing facilities during manufacturing site visit(s) as required for final manufacturing per section 3.2.1. This is because there are typically many customers for a given intermediate product. This means that in most cases, RED or GREY hazards associated with an intermediate product will translate into RED or GREY risks. However, for custom products or those with a limited customer base, conducting site visits at subsequent manufacturing facilities may be possible. If manufacturing site visits have been conducted at all relevant subsequent manufacturing facilities, clauses 3.2.1 a-b may be used (in addition to the other clauses in this section) to alter hazard ratings for the subsequent manufacturing stage. In this case, the assessment results are only valid for the facilities where a site visit has occurred and the certificate must include the following disclaimer: *This product is intended for use as a material input to a finished product. The results of the assessment for this certification are only valid with verification that human and environmental exposure is sufficiently controlled at the finished product manufacturing facility(ies). This requires a manufacturing site visit at the applicable facility(ies).*

at all subsequent manufacturing facilities are trained by the original manufacturer or an entity contracted by the original manufacturer on safe handling of the intermediate product and use of appropriate PPE. Otherwise, the answer to this question is NO.

See Appendix 2 for verification and communication requirements when answering YES to either portion of this question (i.e. b.i or b.i.1). A disclaimer on the certificate is required depending on endpoints of concern and Material Health achievement level.

ii. **HH & EH - Will the chemical be unavailable for environmental (air/water/soil) contact to occur during subsequent manufacturing?** For example, it is sequestered within fully closed and sealed transport, transfer, and dosing systems (as applicable) at all subsequent manufacturing facilities such that there is no opportunity for environmental contact to occur. See Appendix 2 for verification and communication requirements when answering YES to this question.

OR, If environmental contact is expected, does the chemical degrade into a substance of low toxicity? This may be assumed if the chemical's hazard rating for *Persistence* is GREEN or, in the case of the aquatic toxicity endpoints (fish, daphnia, algae), the combined aquatic toxicity flag is YELLOW (i.e. Persistence and Bioaccumulation are both GREEN when the aquatic toxicity hazard rating and risk rating are RED or GREY).

3.2.3 Professional Installation, Application, Use, and/or Maintenance

This stage is only applicable if there is a separate installation, application, maintenance, or in some cases formulation stage that is intended to be carried out exclusively by trained professionals (e.g. installation of building materials, formulation of paint at the point of sale, application of professional paints, and use of professional cleaning products).

For products that may be installed, applied, and/or maintained by either professional installers/contractors or by the general public, apply the section 3.2.4 Use phase questions to installation, application, maintenance, and use, assuming all are done by the general public (this is the more precautionary approach).

The answer must be **YES** to **one** of the following (a-b) in order to assign a YELLOW risk flag for this stage (unless considering an endpoint that may be GREY without affecting the single chemical risk rating as mentioned in Step 1). If the answers are all **NO** or unsure, assign a RED or GREY risk flag as appropriate. If a RED or GREY risk flag is assigned for this stage, the exposure assessment is complete (i.e. there is no need to continue to the questions for use and end-of-use).

a. **HH & EH: Is the chemical reacted into the material such that exposure is not likely to occur during professional installation, application, use, and/or maintenance (as relevant)?** See section 3.2.1 a.i-ii

for sub-questions. Note that certain conditions (e.g. temperature, pH, etc.) and processes (e.g. sawing and grinding) may affect whether or not a substance remains bound within a material. This question must be answered within the range of conditions expected to occur during professional installation and maintenance.

b. **HH & EH: Is exposure via the relevant exposure routes sufficiently controlled during professional installation, application, use, and/or maintenance (as relevant)?** The answers must be **YES** to all questions below pertaining to all relevant exposure route(s) in order to assign a YELLOW risk flag based on question b. Note: Oral exposure may be assumed implausible during professional use.

   i. **HH**: **Will the chemical be unavailable for contact to occur during professional installation, application, use, and/or maintenance (as relevant), such that PPE or administrative controls (e.g. personnel rotation) are not required?** For example, it is sequestered within fully closed and sealed containers and dosing systems and professional users are informed via product labels and/or inserts of the relevant hazards in the event they choose to tamper with the system. If **NO** or unsure, and if chemical has a RED or GREY hazard rating for *Sensitization of Skin and Airways and/or Skin, Eye, and Respiratory Corrosion/ Irritation* go to the next question below:

      1. **HH – Dermal and/or Inhalation (sensitization and irritation/corrosion): Are professional installers, users, and contractors (as applicable) adequately trained regarding safe handling of the product and the use of appropriate PPE?** If PPE is necessary to avoid exposure during subsequent manufacturing, sufficient use of PPE may only be assumed if workers at all subsequent manufacturing facilities are trained by the original manufacturer or an entity contracted by the original manufacturer on safe handling of the intermediate product and use of appropriate PPE. Otherwise, the answer to this question is NO.

   See Appendix 2 for verification and communication requirements when answering YES to either portion of this question (i.e. b.i or b.i.1). A disclaimer on the certificate is required depending on endpoints of concern and Material Health achievement level.

   ii. **HH & EH**: **Will the chemical be unavailable for environmental (air/waster/soil) contact to occur during installation, application, use and/or maintenance (as relevant)?** For example, it is sequestered within fully closed and sealed containers and dosing systems such that there is no opportunity for environmental contact to occur. See Appendix 2 for verification and communication requirements when answering YES to this question.

   OR, If environmental contact is expected, does the chemical degrade into a substance of low toxicity? Environmental exposure during use and subsequent human exposure (e.g. via ground and surface water contamination) in the case of HH endpoints must be assumed for

the following product types without GREEN hazard ratings for *Persistence or, in the case of aquatic toxicity, without GREEN hazard ratings for both Persistence and Bioaccumulation*:

- All wet applied and sprayed on products (e.g. paint, cleaning products)

3.2.4 Use

The use stage is not applicable to the assessment of process chemicals that are not present in the final product.

The use stage includes likely unintended use and installation, application, maintenance, and disassembly for recycling if completed by the non-professional product user.

The answer must be **YES** to **one** of the following (a-c) in order to assign a YELLOW risk flag for this stage. If the answers are all **NO** or unsure, assign a RED or GREY risk flag as appropriate. If a RED or GREY risk flag is assigned for this stage, the exposure assessment is complete (i.e. there is no need to continue to the questions for end-of-use).

a. **HH & EH: Is the chemical reacted into the material in both new and old/worn/damaged product such that exposure is not likely to occur?** The answer to this question will be **YES**, when the chemical is:
   i. Bound to or encapsulated by the material matrix (e.g. titanium dioxide and carbon black as polymer fillers/pigments or within liquids or gels (e.g. paint), other inorganic pigments within polymers, polymer crosslinkers, and colorants fused within a glass matrix, metals within metal alloys when part of the alloy crystallites [also see exceptions for Toxic Metals in section 3.1.1], and quartz (SiO_4) in bulk form or bound within a polymer matrix.) This includes the molecules of the matrix itself, as in the case of solid plastics and other substances with molecules of diameter greater than 950 µm.[34]
   ii. A polymer additive with molecular weight greater than 1000 g/mol. For example, flame retardants and plasticizers with molecular weights greater than 1000 may be considered bound by the polymer. Substances with low molecular weights including residual monomers, some oligomers (e.g. styrene trimers and dimers), some additive flame retardants, residual solvents, and substances that are known to degrade to substances with molecular weights less than 1000 once incorporated into a polymer cannot be assumed to remain within the polymer matrix.

   Certain conditions may affect whether or not a substance remains bound within a material. When exposure to such conditions will occur regularly during use, the effect on the integrity of the material as the product ages must be considered. Conditions to consider in the context of the

[34] Targeted Risk Assessment, Technical Report No. 93., ECETOC, December 2004. See page 109.

questions above include, but are not limited to, exposure to extreme temperatures, acidic to basic pH, ultraviolet (UV) light, solvents (including environmental solutions such as rain water, sweat, etc.), irradiation (microwave, x-ray, and others), air pollution, and mechanical forces/abrasion. These conditions may cause corrosion, break chemical bonds, and result in the release of chemicals or particles that were previously bound within the material. If the material will regularly be exposed to one or more of these conditions, it must be assumed that the chemical with a RED or GREY hazard rating will be released from the material and made available for exposure to occur, unless it can be determined, based on published research, that this will not be the case. "Regularly" is defined as a standard part of the product's intended or likely unintended use. For example, outdoor use products will regularly be exposed to UV. Watches and jewelry will regularly be exposed to human sweat. Tires, brake pads, and shoe soles are regularly exposed to friction and subsequently abrade.

b. Is the product installed or used in such a way that plausible exposure for <u>all</u> relevant exposure routes is ruled out? The answers must be **YES** to all questions below pertaining to all relevant exposure route(s) in order to assign a YELLOW risk flag for the use stage based on question b.

i. HH - Oral: Will the product or part of product be unavailable for oral contact to occur during use? For example, it is installed out of reach, such as within a wall or it is within an assembly that cannot be disassembled using common household tools, OR <u>all</u> of the following conditions are met:

1. The product will not be marketed to/for children (mouthing is assumed to occur in the case of children's products).
2. The product is not meant to be used on/applied to/in contact with the skin during use. (i.e. oral exposure is assumed to occur for the following and similar product types: cosmetics, washing soap, toothbrush, facial tissue, bedding, clothing, etc.).
3. The product will not be used to prepare, hold, or serve food or come into contact with food by some other means (i.e. oral exposure is assumed to occur for the following and similar product types: kitchen counter, table top, desk top, dish detergent, etc.).
4. The product is not a liquid for use in or around the home (the assumption is that children or others may accidently drink such liquids).
5. The product is not intended to be hand-held or used as an arts and craft supply (some users will commonly chew on hand-held devices such as pens or paint brushes, even if they are not intended to be used in such a way).

ii. HH - Dermal: **Will the product or part of product be unavailable for dermal contact to occur during use?** For example, it is installed out of reach (by an installation professional using PPE if necessary per use stage question #2) such as on a ceiling, or within a wall, is within an assembly that is not typically accessed by the user, or is enclosed by another material

(e.g. foam within a polymer layer on an arm rest). If **NO** or unsure, and if chemical has a RED or GREY hazard rating for *Sensitization of Skin and Airways*, go to the next question below.

1. **HH - Dermal (sensitization of skin)**: **Will the product or part of product be used or installed such that repeated (i.e. once a month or more frequent) dermal contact is unlikely to occur?**

iii. **HH - Inhalation/ release of volatiles: Will volatile chemicals be unavailable for contact to occur during use?** The product is used exclusively outdoors. Definition of volatile for the purpose of this question: Boiling point is less than 240°C (the opposite of the threshold indicated in Step 1, point #5). Consider in the context of use stage temperatures.

OR, Has the product passed the Cradle to Cradle Certified VOC testing requirement?

iv. **HH & EH - Can contact of the product or part of product with the environment (air/water/soil) be excluded during use? OR, If environmental contact is expected, does the chemical degrade into a substance of low toxicity?** Environmental exposure during use and subsequent human exposure (e.g. via ground and surface water contamination) in the case of HH endpoints must be assumed for the following product types without GREEN hazard ratings for *Persistence or, in the case of aquatic toxicity, without GREEN hazard ratings for both Persistence and Bioaccumulation*:

- Any liquid or gaseous consumer product (soaps, paints that will be applied by the final user/consumer, spray can propellants, etc.),
- Personal care products (excluding articles as defined by REACH[35]),
- Textiles and clothing that may be washed in water,
- Products that will be used outdoors or are otherwise exposed to water and/or other environmental elements (e.g. tools, outdoor furniture, exterior building components),
- Products known to wear, abrade, and/or release particulates during regular use (e.g. brake pads, tires, shoe soles),
- Products commonly found in roadside litter (e.g. single use packaging including carry out bags)

For products types that are not listed, the default answer to this question is **YES**; lack of environmental exposure during use is assumed.

c. **HH & EH**: **Is the product manufactured with a functional barrier that encloses the material containing the chemical, preventing migration/release of and contact with the chemical?** In order to answer **YES** to this question, testing must have been performed under the range of use

[35] REACH defines an article as an object which during production is given a special shape, surface or design that determines its function to a greater degree than its chemical composition. According to REACH, articles are for example clothing, flooring, furniture, jewelry, newspapers and plastic packaging.

conditions identified (including old/damage/worn conditions and exposure to conditions listed in 3a if relevant) to ensure that this is the case. Examples: Foil or wax layers in food contact packaging or a sealed assembly that restricts release of dry graphite lubricant particles. Note: Test methods acceptable to Cradle to Cradle Certified are still to be determined and approved by C2CPII.

3.2.5 End-of-use

The answer must be **YES** to all of the questions below for **all** end-of-use scenarios accounting for 80% of products sold in order to assign a YELLOW risk flag for this stage. If any answers are **NO** or unsure, assign a RED or GREY risk flag as appropriate (also see exceptions for *Toxic Metals* listed in Step 1).

For products that are just reaching the market, and will take several years until end of use is reached, a realistic forecast of % distribution between the end-of use scenarios listed below would be admissible based on company take-back plans, waste management practices in the regions where the product is sold and recycled, and return rates for similar products. If unsure about the percentages of product or material that will be processed via the common end-of-use scenarios listed below, all end-of-use scenarios are to be considered (although compost only needs to be considered for Biological Nutrients).

For products with a likely use phase greater than 10 years (e.g. building materials that will be installed for long periods of time) and for which a well-developed recycling industry does not already exist (per point b.ii below), all possible end-of-use scenarios must be included in the assessment of the constituent materials unless an active take back program is in place and recovery rate data are available to demonstrate that 80% or more of the material or product sold is recovered and processed via a more limited set of end-of-use scenarios.

a. **Landfill - HH & EH: Will the chemical remain in the material matrix and therefore remain in the landfill OR degrade into substance of low toxicity if released from landfill? Alternatively, is the dermal route of exposure the only route of concern?**
    i. If the dermal route of exposure is the only route of concern, the default answer to this question is **YES** (i.e. skin contact and dermal exposure are not considered relevant to the landfill scenario).
    ii. If the hazard rating is GREY for *Sensitization of Skin and Airways* and/or for *Skin, Eye, and Respiratory Corrosion/Irritation* this will not affect the risk rating for the landfill scenario.
    iii. **For chemicals <u>within polymers or glass, or metals</u>** that were determined to be bound within the material matrix per use stage question 3a, the default answer to this question is **YES**. However, it may not be assumed that products with stable barriers maintain their integrity within a landfill (as in 3c).[36]

[36] The Fate of Heavy Metals in Landfills: A Review, 2006 (accessed May 17, 2017)

iv. **All other chemicals and endpoints:**

1. When the hazard rating for *Persistence* is YELLOW or GREEN, the default answer to this question is YES.
2. In all other cases, it is assumed that release to the environment (air/water/soil) occurs and subsequent human exposure may occur (e.g. via ground and surface water contamination resulting from landfill leaching).

b. **Recycling - HH & EH: Is release of and exposure to the chemical unlikely during recycling?**

i. **When recycling is done by the manufacturer or other known manufacturers:** Ask the same questions that were posed for the final manufacturing stage in the recycling context.

ii. **When a well-developed recycling industry for the material in question exists that is outside the manufacturer's control:** Consider scientific studies and other publicly available information to determine if the chemical is of HH or EH concern during recycling. This may be done for the commonly recycled metals (aluminum, steel, copper), glass, and paper. If there is no information available regarding exposure to or fate of the chemical during recycling processes, or the evidence is insufficient to indicate low risk, a RED or GREY hazard rating will result in a RED or GREY risk flag. It cannot be assumed that sufficient PPE or controls on release to the environment will be used by all recyclers if these would be necessary to prevent exposure due to the global nature of the scrap trading and recycling industry.[37]

iii. **When a recycling infrastructure is not well-developed and is also outside the manufacturer's control** (assumed for materials that are not listed above in point ii): It must be assumed that the material will be landfilled and/or incinerated. See the questions for those end of use scenarios in this case. (Note: The 80% still applies here, and in most cases both landfill and incineration will have to be considered.)

c. **Compost - HH & EH (Biological Nutrients only): Does the chemical degrade or react into a substance of low toxicity in typical home or industrial (as relevant) composting conditions?** Combined aquatic toxicity risk flags of RED or GREY are not altered (e.g. if the combined aquatic toxicity risk flag is RED, the single chemical risk rating will be RED for the composting scenario). For all other endpoints, when the chemical's hazard rating for *Persistence* is GREEN, the default answer to this question is **YES**. In all other cases, it is assumed that release to the environment

[37] Locating and Estimating Air Emissions from Sources of Lead and Lead Compounds, US EPA, 1998. "Each processing step in the secondary aluminum industry is a potential source of lead emissions, which are generally emitted as PM. Lead emissions will be a small fraction of total particulate emissions and will vary with the lead content of the scrap." AND
Inhalation Exposure in Secondary Aluminium Smelting, Elsevier Science Ltd on behalf of British Occupational Hygiene Society, 2001 Heavy Metals in Waste, EU Commission, 2002. "Cadmium, lead and mercury may be present as contaminant in iron and steel scrap, making secondary steel production an important source of release of these metals to air. Chromium and to some extent lead is also used as alloy in steel. The heavy metals may as well be present in aluminium scrap, but compared to steel scrap the total turnover with aluminium scrap is small."

(air/water/soil) occurs and subsequent human exposure may occur (e.g. via ground and surface water contamination).

d. **Incineration and uncontrolled burning - HH & EH: Is the chemical free of organohalogens and toxic metals?** This end-of-use scenario only concerns the *Toxic Metals* and *Organohalogens* endpoints (and no others). For these chemical classes, the hazard rating is equal to the risk rating due to the likely release of highly toxic substances during combustion. Therefore, a material containing an organohalogen or toxic metal that may end up being incinerated or burned will always be X assessed with several exceptions for the toxic metals as described in Step 1. Furthermore, this scenario must be considered likely for the toxic metals and organohalogens in all cases other than for the exceptions described in Step 1. In the case of the Step 1 exceptions the answer may be NO to this question and a YELLOW risk flag may be assigned to the *Toxic Metals* endpoint. Otherwise, if the answer to this question is NO, a RED risk flag must be assigned.

e. Release to the Environment (e.g., for liquid consumer products that are typically flushed/released to a sewer system)– refer to Use Phase section 3.2.4 b.iv.

3.2.6 Out of Scope Stages and Processes

The following stages and processes are currently excluded from the exposure assessment:

- Raw material extraction and production and any manufacturing steps that occur prior to the final manufacturing stage for the product under review.
- Material recovery processes that occur prior to disposition in the listed end-of use scenarios (e.g. building demolition and resizing/cutting of materials prior to handling at a recycling facility).
- Handling of materials at transfer stations, landfills, or incineration facilities prior to placement in a landfill or incineration.

Note that for any chemical that is subject to review (as defined by the Cradle to Cradle Certified Product Standard) but that is out of scope for the exposure assessment itself these stages and processes are still addressed. For example, the exposure method may not be applied to chemicals of regulatory concern, PBTs, organohalogens, or toxic metals as defined in section 3.1. These chemicals are required to be phased out of certified products at varying achievement levels (depending on the specific issues of concern) and will not be present at all in Gold and Platinum certified products.

4 DEFAULTS FOR COMMON CHEMICALS

This section provides examples of common chemicals used in consumer products, their context, and their typical assessment ratings:

1. The following substances are carcinogenic via inhalation. When incorporated into a polymer, exposure to these chemicals is assumed to be unlikely to occur in all use cycle stages. The polymer containing these substances may be C assessed.
    a. Titanium dioxide, CAS 13463-67-7
    b. Carbon black, CAS 1333-86-4 (Note: If there is potential exposure to PAHs, for example when carbon black containing PAHs is used in toys, this must be considered as part of the assessment as well per the Cradle to Cradle Certified Product Standard Version 3.1).
    c. Silica dust, crystalline, in the form of quartz or cristobalite, CAS 14808-60-7

    (However, when the polymer itself is the subject of certification, and hence exposure may occur during the final manufacturing stage, exposure to these materials needs to be considered.)

2. Antimony trioxide: Antimony trioxide is typically present above 100 ppm in PET when used as the catalyst and is carcinogenic via all routes of exposure (oral, dermal, inhalation). PET-containing antimony trioxide will always be X assessed. Exposure is deemed likely during end-of-use when the polymer is burned or recycled (in particular if recycled for textile applications where antimony leaches from polymers during the dyeing and washing processes).

3. Aluminum alloy with intentionally added lead above 100 ppm (e.g. to improve machinability): Lead (CAS 7439-92-1) is a toxic metal with RED hazard ratings for *Carcinogenicity*, *Endocrine Disruption*, *Reproductive Toxicity, Mutagenicity, Neurotoxicity*, and combined aquatic toxicity (PBT). Aluminum is highly recycled. Release of lead to the environment during secondary aluminum processing does occur and is of concern (both particulates and volatilized lead are released per the US EPA and others). For this reason, lead that is intentionally added at 100 ppm or above will receive a RED risk flag for the *Toxic Metals* endpoint and the aluminum will be X assessed. Exception: See below.

4. Aluminum alloy containing recycled content: Some aluminum alloys (e.g. die cast aluminum A380) contain between 500 and 3,500 ppm lead.[38, 39] An exception to the 100 ppm threshold has been instituted in the case of aluminum and other metals containing recycled content. The reason for the exception is that it is not currently feasible in many cases to reduce the lead concentration below 100 ppm when recycled content is used. This is due to the lead content of the recycled material. The threshold in this case aligns with RoHS (0.4% at time of publication; likely to be

[38] Aluminum Alloys for die casting according to the Japanese Standards (accessed on March 15, 2017).

[39] Aluminium-Gusslegierungen (accessed on March 15, 2017).

lowered to 0.1% or 1000 ppm in the future for aluminum). The higher threshold may only be applied in the case that:

- **a.** Sufficient PPE and controls on environmental release are used during the manufacturing stage.
- **b.** The material/product meets the requirements listed in use stage question 3a and 3b (i.e. it will not regularly be exposed to conditions resulting in release of the lead AND it is not a product marketed to children, used to cook food, etc.).

If the material meets the requirements above, it may be C-assessed when lead is present at 100-4000 ppm.

5. Steel alloy containing nickel. Nickel (CAS 7440-02-0) is a toxic metal with RED hazard ratings for *Carcinogenicity* (with some conflicting data), *Oral, Dermal, and Inhalation Toxicity, Sensitization of Skin and Airways* and combined aquatic toxicity. Nickel is bound within the steel alloy such that exposure via any route, as well as release to the environment during the use stage, is unlikely. It is assumed that sufficient PPE is in use during manufacturing. In addition, steel is highly. The steel alloy may in this case receive a C assessment. However, if the steel alloy will be in dermal contact as part of its intended use, sensitization may occur. Exposure to human sweat may result in release of nickel ions and subsequent dermal absorption. Therefore, for products that will be in contact with human skin (and presumably sweat) during their intended use, nickel will receive a RED risk flag for *Sensitization of Skin and Airways* and *Toxic Metals* and the alloy will be X assessed (and may be further restricted under v4 as per the current Restricted Substances List (RSL) draft). See Step 1 for additional information.

APPENDIX 1 APPLYING LIMIT VALUES TO ASSESSMENT OF EFFLUENT AND AIR

1.1 Effluent: Analytical Testing Methods & Limit Values

If a chemical is expected to be present in water and is still x or GREY assessed after completing the steps above, the effluent may optionally be tested to determine if individual chemicals are present below detection limits, below safe limits (if available), or are of low toxicity, as described below. Alternatively, both incoming water and effluent may be tested to determine if the concentration within the effluent is at or below the incoming concentration. In cases where effluent is discharged to a third party treatment facility, the required limits may be met either by the final manufacturing stage facility or by the third party treatment facility.

If testing shows that a chemical is below the required limits within effluent, or present in effluent at or below the incoming concentration[40], a RED or grey hazard rating may be assigned a YELLOW risk flag **in the context of water** (sludge and air may still need to be considered per the points above). The following approaches are acceptable depending on the chemical, region, etc. as noted.

1. **For regulated substances:** national or international objective limits for water bodies may be applied to the effluent as it leaves the facility (unless permit limits are lower in which case those take precedence).[41] The limits indicated in the following references must be achieved using the associated test methods. Exception: if feasible detection limits are above safe limits (e.g., the limits of quantification (LOQ) are above the Environmental Quality Standards (EQS) using the EU terminology), testing shall not be used to alter a RED hazard rating.[42]
    a. If a facility is in the EU: *Directive 2008/105/EC* on environmental quality standards (EQS) in the field of water policy applies. If lower limits have been set by the relevant member state, those limits take precedence.
    b. If a facility is in the US: EPA priority pollutants and test methods including the listed detection limits apply unless objective limits have been set at the state

[40] If the applicant is actively choosing to use contaminated water this approach may not be used to apply a YELLOW rating - for example, if wastewater from another facility is used as an input to the final manufacturing stage. This approach does apply when, for example, water purchased from the municipality already contains high levels of a substance under consideration.

[41] Note: Technology based effluent limitations may not be employed (e.g. TBELs in the US and Best Available Technique/BAT based limits in the EU) because these are not necessarily safe limits.

[42] Note: some regulatory limits for priority substances are set below the limits of quantification: European Union, Technical Report on Aquatic Effects Based Monitoring Tools, 2014, see page 19. https://circabc.europa.eu/sd/a/0d78bbf7-76f0-43c1-8af2-6230436d759d/Effect-based%20tools%20CMEP%20report%20main%2028%20April%202014.pdf

level in which case those must be met.[43] Note that some states defer to the National Recommended Water Quality Criteria - Human Health and Aquatic Life. If there are limits indicated for both chronic and acute toxicity (as there are in the two prior links), the lower limit must be applied.

c. EU facilities may apply the limits set per the US references above for any substance that is not regulated in the EU (and vice versa).

d. For other regions: If similar objective limits have been set for the relevant water body that have been determined based on what is safe for humans and the environment, those limits may be applied. If not, the lower of the EU or US relevant limits above must be employed.

2. **For non-regulated substances** the following approaches may apply (i.e., the applicant and assessor select a method from those listed below as deemed most appropriate):

   a. For aquatic toxicity endpoints: the complete suite of Whole Effluent Toxicity (WET) testing may be employed. If the effluent is tested and exhibits low toxicity to aquatic life (i.e. the result of the tests = pass which means no significant difference between the effluent and the control), a YELLOW risk flag may be assigned. Note: WET testing is already required in the US for permit compliance in many cases and those results may be used to show lack of aquatic toxicity for Cradle to Cradle Certified. Conducting new WET testing for the purposes of certification (when not already required by permits) is an option, but note that these tests do require live animal testing and so are not recommended.

   b. Otherwise, the following limits apply and the assessor and/or an ISO 17025 certified laboratory may propose appropriate test methods.

      i. For Aquatic and Terrestrial Toxicity: A Predicted No Effect Concentration (PNEC)[44,45], using assessment factors defined by the European Commission shall be applied as the effluent limit (see link in footnote below for calculation methods and Appendix 1 for examples of how it is applied).

      ii. For the Sensitization, Oral, and Dermal Toxicity: The mixture rules may be applied to effluent. i.e., the concentration needed for assigning a YELLOW risk flag as defined by the mixture rules shall be used as the limit. See the Appendix 1 for further detail.

      iii. For the Skin, Eye, and Respiratory Corrosion/Irritation: Chemicals with a RED hazard rating for this endpoint that are irritating due to pH, may affect the pH of the effluent. In this case, permit or international guideline limits for pH apply. Substances that are grey for this endpoint

[43] For example see: US EPA, Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California. 40 CFR Part 131, Thursday May 18, 2000.

[44] http://www.chemsafetypro.com/Topics/CRA/How_to_Calculate_Predicted_No-Effect_Concentration_(PNEC).html

[45] https://echa.europa.eu/documents/10162/13632/information_requirements_r10_en.pdf

are out of scope for effluent assessment (i.e., if grey for this endpoint, a YELLOW risk flag may be assigned in this context)

iv. Otherwise, an ISO 17025 certified laboratory may propose feasible detection limits. If effluent is tested and the substance shown to be below feasible detection limits, then YELLOW risk flag may be applied. (This is the same as the Version 3.1 approach.)

1.2 Air: Analytical Testing Methods & Limit Values

As for effluent, analytical testing of air is not required. However, if a chemical is expected to be present in air (i.e., meets condition **1c** above) and is still x or grey assessed after completing the steps above, the air may be tested to determine if individual chemicals are present below the required limits as described below. If a chemical is present below the required limits, a RED or grey hazard rating may be assigned a YELLOW risk flag **in the context of air** (water and sludge including air scrubber sludge may still need to be considered per the points above). Note that the approach for air is somewhat different from that of water because there is not currently a methodology for calculating PNEC in air nor a set of standardized toxicity tests applicable to outdoor air that can be applied. In addition, fewer substances are individually regulated in the context of air compared to water. The following approaches apply:

1. **For regulated substances:**
    a. National or international objective limits for ambient air quality may be applied to the air as it leaves the air control equipment used at the facility.[46] If limits have not been set in one region, those set in other regions may be applied (e.g. the EU has set limits on benzene and PAHs while the US has not).
    b. If objective limits have not been set (or if permit limits are lower than the objective limits, which is unlikely), the limits set by the permits apply.
    c. If permits do not exist, or do not indicate limits for the substance in question, limits set by the International Finance Corporation (IFC)[47] for the industry in question or similar (if industry specific limits are not available) apply.
    d. When total VOCs are limited by permits or the IFC guidelines, these limits apply in addition to the approach described in the non-regulated substances section that follows.
2. **For other non-regulated substances:**
    a. If there is a RED hazard rating for the Inhalation Toxicity endpoint, or for Respiratory Sensitization, the mixture rules may be applied to the concentration

[46] EU: http://ec.europa.eu/environment/air/quality/standards.htm US: https://www.epa.gov/criteria-air-pollutants/naaqs-table US, California: https://www.arb.ca.gov/research/aaqs/caaqs/caaqs.htm WHO: http://www.who.int/mediacentre/factsheets/fs313/en/

[47] IFC: http://www.ifc.org/wps/wcm/connect/topics_ext_content/ifc_external_corporate_site/sustainability-at-ifc/policies-standards/ehs-guidelines

in air measured as it leaves the air control equipment (i.e. the concentration needed for assigning a YELLOW risk flag as defined by the mixture rules may be used as the limit).

b. For substances that are toxic via inhalation that are not covered by the mixture rules (e.g. RED hazard for human health endpoints such as carcinogenicity but not a regulated substance), the assessor and/or an ISO 17025 certified laboratory may propose appropriate test methods and detection limits. If air is tested and the substance shown to be **below feasible detection limits** in air as it leaves the control equipment, then a YELLOW risk flag may be applied.

c. **Otherwise, the assessor must review the scientific literature to determine if there are any known issues of high concern associated with release of the substance to air.** Currently there is not a specific hazard endpoint aside from the 'other' endpoint that addresses acidification or eutrophication. These issues must be taken into consideration as part of the research (note: this may be covered under the regulated substance section for some industries e.g. permits may include limits for sulfur and nitrogen oxides, ammonia, etc.). The research should also include determination of whether or not hazardous substances or reactants are likely to be returned to soil and/or water due to land deposition processes. If yes, then assessment in those contexts is also required. If no issues are identified, a YELLOW risk flag may be applied in the context of air. In other words, **endpoints that are GREY may be out of scope in the context of release to air**. If issues of high concern are identified, the assessor and/or an ISO 17025 certified laboratory may propose appropriate test methods and detection limits. If air is tested and the substance shown to be below feasible detection limits in air as it leaves the control equipment, then a YELLOW risk flag may be applied.

1.3 Sampling & Testing Frequency

Sampling: For regulated substances, sampling methods required by permits must be followed. Otherwise, for effluent, the sampling methods required for the Zero Discharge of Hazardous Chemicals (ZDHC) program or equivalent are required.

Testing frequency: Must align with permit requirements if considering regulated substances and/or if using test results that are also required by permits (e.g., Whole Effluent Toxicity testing). Otherwise, bi-annual (i.e., two per year) testing is required. If all tests have been in compliance after a two year period (four tests total), further tests are not required unless there have been changes in the manufacturing process. If changes have occurred, another two year period of bi-annual tests must be completed.

1.4 Assessment of Effluent Using the Mixture Rules

The Mixture Rules apply to a subset of hazard endpoints as follows: Oral, Dermal, and Inhalation Toxicity, Irritation, Sensitization, and Aquatic Toxicity (Acute & Chronic).

The Cradle to Cradle Material Health Assessment Methodology Mixture Rules may be applied directly to effluent prior to completing the exposure assessment or deriving the combined aquatic toxicity risk flag for all covered endpoints except for Aquatic Toxicity (PNEC must be used for aquatic toxicity). In other words, the effluent may be assessed as a "material". **This approach may only be used for simple mixtures (defined as 10 components or less)** due to the increased likelihood of interactions occurring between mixture components as complexity increases. If the substance is also potentially entering the sludge and/or released to air, that must also be considered and assessed as described in the Exposure Assessment Method: Final Manufacturing Stage section above.

EXCEPTION: This approach may not be used for substances that are regulated in the context of industrial effluent.

In order to apply the Mixture Rules, **it will be necessary to determine concentrations for and assess ALL chemicals present in effluent** as opposed to only those chemicals relevant to the product to be certified. All chemicals present in intentional product input formulations and process chemical formulations at ≥ 1000 ppm, that are also potentially entering effluent, must be part of the assessment. Again, this applies to all products and processes at the facility, not only those used to manufacture the certified product.

Estimated concentrations of chemicals within the effluent as it leaves the facility, based on analytical testing or maximum theoretical concentrations, may be used when applying the Mixture Rules.[29, 30] Estimated concentration(s) must equal the highest of the values obtained via analytical testing (if testing is conducted). See Analytical Testing sections above for methods and frequency. If substances are released only periodically, sampling must coincide to capture concentration spikes.

1.5 Assessment of Effluent Using the Predicted No-Effect Concentration (PNEC)

Assessment of effluent using the Predicted No-Effect Concentration (PNEC) applies to Aquatic Toxicity hazard endpoints (Algae, Daphnia, and Fish) and the Terrestrial Toxicity hazard endpoint. To use this route of evaluation, PNECs need to be calculated for every environmental compartment (water [fresh, and marine], soil, sediment) for which toxicity data are available and exposure to effluent is feasible (algae/daphnia/fish in water, soil-living organism for soil, sediment-living organism for sediment). Each PNEC value will then be compared to the concentration of the substance in the effluent. If the concentration of the substance in the effluent is greater than the respective PNEC value, the substance will receive a RED risk flag for the toxicity endpoint relevant to the particular PNEC (in the case of aquatic toxicity, the PNEC-*fresh water* and PNEC-*marine water* corresponds to all

aquatic toxicity endpoints, so a concentration > PNEC would result in a RED flag for all three aquatic toxicity endpoints).

Which PNECs Need to Be Calculated

The PNEC for each environmental compartment for each substance needs to be calculated if data relevant to that environmental compartment is available as follows:

Environmental Compartment	**PNEC type**	**Calculate this PNEC if this data is available**
Fresh Water	PNEC-*fresh water*	The lowest value (EC50, LC50, NOEC) from one of the three aquatic toxicity endpoints (daphnia, algae, fish)
Marine Water	PNEC-*marine water*	Only derive if exposure to marine water is possible. If no marine-life aquatic toxicity data is available, PNEC-*marine water* = PNEC-*fresh water*/10
Soil	PNEC-*soil*	NOEC/EC10 values for sediment living organisms (equal to the lowest value of NOEC/EC10 from data available)
Sediment	PNEC-*sediment*	NOEC/EC10 values for sediment living organisms (equal to the lowest value of NOEC/EC10 from data available)
Sewage Treatment Plant Microorganism, Air, Predator	PNEC-*STP*, PNEC-*predator*, PNEC-*air*	Not necessary to calculate for this requirement.

How PNECs are Calculated

PNECs for each environmental compartment are derived from the respective lowest data values relevant to each environmental compartment (see table above) divided by a particular assessment factor. The assessment factors are calculated based on the type of data that is available as described in the following table:

PNEC Type	Available Data	AFs
PNEC-*water* or PNEC-*soil*	At least one short-term L(E)C50 from each of three trophic levels	1000
	One long-term EC10 or NOEC from one trophic level	100
	Two long-term results (e.g. EC10 or NOECs) from species representing two trophic levels	50
	Long-term results (e.g. EC10 or NOECs) from at least three species representing three trophic levels	10
	Species sensitivity distribution (SSD) method	1-5
	Field data or model ecosystems	Case by case
PNEC-*STP micro-organism*	Short-term EC50 from activated sludge respiratory inhibition	100
	Long-term NOEC from activated sludge respiratory inhibition or biodegradability test	10
	Long-term NOEC from inhibition of nitrification bacteria	1
PNEC-*sediment*	One long-term test (NOEC or EC10) on one sediment living organism	100
	Two long-term test (NOEC or EC10) with two species of sediment living organism	50
	Three long-term test (NOEC or EC10) with three species of sediment living organism	10

Example of PNEC calculation and comparison to effluent concentration

Example: Substance A

Toxicity Data

- Daphnia Toxicity, LC50 - 8mg/L, NOEC - 2 mg/L.
- Algae Toxicity, LC50 - 5 mg/L.
- Fish Toxicity, LC50 - 3 mg/L.
- No data on terrestrial toxicity.
- No data on marine-life toxicity.

Concentration Data

- Substance A is present at 0.01 mg/ml in the effluent sample

Calculating PNEC values:

PNEC-*fresh water:* Lowest value is 2 mg/L, and there is one long term NOEC value from one trophic level so the assessment factor is = 100. The calculated PNEC-freshwater value is then 0.02 mg/L.

PNEC-*marine water:* The effluent in this assessment is predicted to be released into the marine environment. Since no data on marine animals was collected, the PNEC-marine

water value is then calculated from the PNEC-freshwater value (by a factor of 10). Therefore the PNEC-marine water value is 0.002 mg/L.

Comparison to concentration data

- Although the substance is at a concentration in the effluent sample lower than the PNEC-fresh water value, it is higher than the PNEC-marine water value. Therefore, it will receive a RED flag for all three aquatic toxicity endpoints.

APPENDIX 2 INTERMEDIATE AND OTHER PROFESSIONAL USE PRODUCTS: VERIFICATION & COMMUNICATION REQUIREMENTS

This appendix provides verification and communication requirements applicable to Sections 3.2.2 Subsequent Manufacturing and 3.2.3 Installation, Application, Use, and Maintenance.

A. Scenario: Human and/or environmental exposure is completely avoided, PPE is not required

Applicable to the Following Endpoints: All, excluding cases where an exposure assessment is not allowed per Section 3.1.1 (i.e., chemicals of regulatory concern, PBTs, organohalogens, toxic metals unless there are exceptions noted in Section 3.1.1).

Verification Requirements – All of the following are required to verify that human and/or environmental exposure (as relevant) is not plausible. The answers must be **YES** to all questions (a-c) below:

a. **Does the applicant sell the product exclusively to corporate, professional customers?**
    i. The applicant must provide evidence that the product is sold exclusively to corporate, professional customers. An attestation from the applicant will be accepted as evidence.

b. **Does the applicant adequately inform customers regarding the relevant hazard(s)?**
    i. The applicant must provide evidence that customers are adequately informed regarding the relevant hazard(s), as applicable. Information must be provided on the safety data sheet, product label or insert, and the company website.

c. **Are fully closed and sealed exposure avoidance system(s) or process(es), as required by the applicant, applicable and effective?** Where fully closed and sealed exposure avoidance system(s) or process(es) are used during transport, transfer, manufacturing, or professional installation, application, use, or maintenance, the following must be provided to demonstrate that all relevant customers are using the systems described:
    i. A description and photos of the system(s) or process(es).
    ii. Evidence that the exposure avoidance system or process in place is common industry practice as evidenced by a technical standard (e.g., ISO) or guidance provided by an applicable trade association, industry group, or authoritative body.
    iii. A summary of a literature search that was conducted to determine if existing evidence indicates that the exposure avoidance system(s) or process(es) are not effective (e.g., a search of any applicable and publicly available occupational health and safety records and

literature). If applicable incidences of worker health and safety among the relevant group of professionals in the applicable markets are high despite commonly used exposure avoidance system(s) or process(es), then a RED risk flag must be assigned. The following steps are recommended for use when performing this literature search:

- **Identify relevant literature**: Begin by identifying and compiling all relevant occupational health and safety records, technical standards, industry guidelines, and scholarly articles related to the exposure avoidance system(s) or process(es) in question. This could involve searching the following databases or resources:
    - Health and Safety Executive (HSE) database
    - European Agency for Safety and Health at Work (EU-OSHA)
    - Institut National de Recherche et de Sécurité (INRS)
    - The German Social Accident Insurance (DGUV)
    - Cochrane Library
    - FDA Adverse Event Reporting System (FAERS)
    - Occupational Safety and Health Administration (OSHA) database
    - National Library of Medicine, PubMed
    - NIOSH Data and Statistics Gateway
- **Evaluate effectiveness**: Specifically look for literature that evaluates the effectiveness of the exposure avoidance system(s) or process(es). This may involve examining studies that have measured exposure levels in situations where these systems or processes are used, or research that analyzes incidence rates of occupational illnesses or injuries among professionals using these systems.
- **Identify incidences of worker health and safety**: Also, look for evidence indicating high incidences of worker health and safety problems among the relevant professional groups, despite the use of the exposure avoidance system(s) or process(es). This could involve reviewing occupational health and safety reports, compensation records, or other documents detailing workplace injuries or illnesses.

When determining if the incidences of worker health and safety are sufficiently high to assign a red risk flag, an overall weight of evidence must be used. In other words, a risk flag must not be assigned based on a single study or source, but must reflect a broad consensus in the literature.

iv. A site visit at a primary facility must also be conducted to verify that the system(s) or process(es) in place are fully functional. In lieu of an in-person site visit, an online video inspection that covers all requirements to confirm functionality of the system(s) or

process(es) is acceptable. A description of the site visit or video inspection, including observations of the system(s) or process(es) and a determination of their proper functionality and effectiveness, is also required.

Communication Requirements - The Material Health Certificate and Cradle to Cradle Certified certificate must note the following if applying at Silver, Gold, or Platinum level in Material Health and the Material Health level is dependent upon the following assumptions:

"This [intermediate] product was assessed exclusively for application by professional [insert type of manufacturer e.g. can manufacturers] employing fully closed and sealed [transport, manufacturing lines, and/or dosing systems as relevant] to protect [workers and/or the environment] from [list endpoints of concern e.g. endocrine disrupting, carcinogenic, etc.] substances.

[If relevant, add: The concentration of the certified [intermediate] product in final products sold to the general public must be at or below [X] for the assessment results to be valid.]

The requirements for certification have only been met under these conditions."

B. Scenario: Human exposure is avoided through effective hazard communication and availability of PPE training for professional users.

Applicable to the Following Endpoints <u>Only</u>:

- Sensitization of Skin and Airways.
- Skin, Eye, and Respiratory Corrosion/Irritation.

Verification Requirements – All of the following are required to verify that exposure to sensitizers and corrosive or irritating substances is not plausible during professional use. This section is required for colorants assessed per the Colorants Assessment Methodology and for other substances assessed per this document. The answers must be **YES** to all questions (a-d) below:

a. **Does the applicant sell the product exclusively to corporate, professional customers?**
   The applicant must provide evidence that the product is sold exclusively to corporate, professional customers. An attestation from the applicant will be accepted as evidence.

b. **Are customers adequately informed regarding the relevant hazard(s)?** [48]
   The applicant must provide evidence that customers are adequately informed regarding the sensitization and/or corrosion/irritation hazard(s), as applicable. The answer must be YES to either of the following questions:
   i. **Are the relevant hazard(s) communicated via regulatory pathways (e.g., safety data sheet or other regulatory document)?**
      Information must be provided on the safety data sheet (SDS) or other regulatory document(s) that effectively inform users of relevant hazards. When determining how hazards are communicated, assessor must consider EU & US OSHA requirements for the relevant industry, OSHA compliance, and SDS indications. Hazard communication through SDS or other regulatory pathways fulfills this requirement.
   ii. **In regions where hazard communication is NOT required by regulation, does the applicant proactively and effectively communicate relevant hazards directly to downstream users via non-regulated pathways?**
      In regions where hazard communication is not required by local regulations, hazard

[48] Note: For some intermediate products, regulatory compliance according to clauses 2.B.i. and 2.C.i. may occur only in specific regions where the product is sold. In these cases, clauses 2.B.i. and 2.C.i. may be used (in addition to the other clauses in this section) to alter hazard ratings for the subsequent manufacturing stage. In this case, the assessment results are only valid for the regions where regulations meet the requirements, and the certificate must include the following disclaimer: "This product is intended for use as a material input to a finished product. The results of the assessment for this certification are only valid with verification that local regulations sufficiently require effective hazard communication and use of personal protective equipment at finished product manufacturing facility(ies)."

information must be provided on the product label, technical data sheets, or the company website.

c. Are downstream customers trained and required to use personal protective equipment? [49] The answer must be **YES** to either of the following questions:

i. Does the applicant sell exclusively to downstream users that are in regions where PPE training and use is required by regulation?

The applicant must provide evidence that the product is sold exclusively in regions where regulations on the training and use of PPE exist. An attestation from the applicant will be accepted as evidence. This pathway currently applies only to countries assumed to have well-developed and enforced worker health and safety regulations: Countries within the EU, Switzerland, United Kingdom, United States, Canada, and Japan. Note: This list may be extended in the future.

ii. In regions where PPE training and use is NOT required by regulation, has the applicant taken proactive steps to train, or to make training available to, all downstream professional users covering all applicable hazard endpoints?

The applicant must provide evidence that customers are adequately trained regarding safe handling of the product, such that it is possible to state that contact or repeated (i.e., once a month or more frequent) contact for corrosion/irritation and sensitization respectively is unlikely to occur. Training may be done by the applicant, an entity contracted by the applicant, or an industry association to which the applicant belongs. Note: This requires proactive action by applicants to ensure that training is provided to professional users. All of the following are required in order to answer 'yes' to this question (Appendix 2B, c, ii):

- Description of the applicant company's procedure for training professional customers on safe handling of the product, including a list of designated staff (i.e., job titles).
- Job description(s) for staff providing safety trainings. Training of customers on the safe use of the applicant's products must be a defined responsibility for one or more staff.
- Safety training materials as provided to the customer. For example, PowerPoint presentations and/or online guidance and resources. The training information must specifically address the hazards and risks relevant to the certified product(s).

[49] Note: For some intermediate products, regulatory compliance according to clauses 2.B.i. and 2.C.i. may occur only in specific regions where the product is sold. In these cases, clauses 2.B.i. and 2.C.i. may be used (in addition to the other clauses in this section) to alter hazard ratings for the subsequent manufacturing stage. In this case, the assessment results are only valid for the regions where regulations meet the requirements, and the certificate must include the following disclaimer: "This product is intended for use as a material input to a finished product. The results of the assessment for this certification are only valid with verification that local regulations sufficiently require effective hazard communication and use of personal protective equipment at finished product manufacturing facility(ies)."

- Evidence of proactive engagement with customers to encourage participation in trainings and/or make them aware of the training offerings. For example, emails to customers to announce training events and/or offerings.
- Evidence that the training has occurred. For example, past meeting agendas and/or evidence of customers accessing and completing online training offerings.

d. Are the recommended measures to control exposure using personal protective equipment (PPE) effective? A summary of a literature search that was conducted to determine if existing evidence indicates that the recommended safety measures are not effective must be provided. If incidences of corrosion/irritation and/or sensitization as applicable among the relevant group of professionals in the applicable markets are high despite commonly used protective measures (assuming the commonly used measures are the same as those recommended by the applicant), then a RED risk flag must be assigned. The following steps are recommended for use when performing this literature search:

- **Identify relevant literature**: Begin by identifying and compiling all relevant occupational health and safety records, technical standards, industry guidelines, and scholarly articles related to the exposure avoidance system(s) or process(es) in question. This could involve searching the following databases or resources:
  - Health and Safety Executive (HSE) database
  - European Agency for Safety and Health at Work (EU-OSHA)
  - Institut National de Recherche et de Sécurité (INRS)
  - The German Social Accident Insurance (DGUV)
  - Cochrane Library
  - FDA Adverse Event Reporting System (FAERS)
  - Occupational Safety and Health Administration (OSHA) database
  - National Library of Medicine, PubMed
  - NIOSH Data and Statistics Gateway
- **Evaluate effectiveness**: Specifically look for literature that evaluates the effectiveness of the exposure avoidance system(s) or process(es). This may involve examining studies that have measured exposure levels in situations where these personal protective equipment are used, or research that analyzes incidence rates of occupational illnesses or injuries among professionals using these equipment.
- **Identify incidences of worker health and safety**: Also, look for evidence indicating high incidences of worker health and safety problems among the relevant professional groups, despite the use of personal protective equipment. This could involve reviewing occupational health and safety reports, compensation records, or other documents detailing workplace injuries or illnesses.

When determining if the incidences of worker health and safety are sufficiently high to assign a red risk flag, an overall weight of evidence must be used. In other words, a risk flag must not be assigned based on a single study or source but must reflect a broad consensus in the literature.

Communication Requirements - The Material Health Certificate and Cradle to Cradle Certified certificate must note the following if applying at Gold or Platinum level in Material Health and the Material Health level is dependent upon the following assumptions:

"This product was assessed exclusively for use by professional [insert type of manufacturer] trained in the proper handling and use of protective equipment for [sensitizing and/or corrosive and/or irritating] [insert type of material].

[If relevant, add: The concentration of the certified [intermediate] product in final products sold to the general public must be at or below [X] for the assessment results to be valid.]

The requirements for certification have only been met under these conditions."