Updates to the Cradle to Cradle Certified® Material Health Assessment Methodologies for Use in Version 4.0 Assessments

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1 Introduction

As part of the Cradle to Cradle Certified® Product Standard Version 4.0 development process, several updates were made to the Cradle to Cradle Certified® Material Health Assessment Methodology and supporting methodologies. **These updates are provided in this document and are required for use in all Material Health assessments conducted for certification of products to the draft and final versions of the Cradle to Cradle Certified Version 4.0 standard.**

2 Updates to the Material Health Assessment Methodology

The following updates apply to the Material Health Assessment Methodology (the main Material Health assessment methodology document).

2.1 Changes to the Persistence Endpoint

In order to align the hazard level cut-offs with the ECHA/REACH definitions of persistent, bioaccumulative, and toxic substances (PBTs) and very persistent, very bioaccumulative substances (vPvBs), the persistence endpoint criteria have been modified as shown in Table 1 below.

Table 1 - Comparison of Version 3.1 and Version 4.0 hazard rating criteria for the Persistence endpoint.

GREEN	YELLOW	RED	PURPLE[1]	GREY
Version 3.1 Persistence Hazard Rating Criteria:				
T1/2 < 30/90 days in water/ soil or sediment; Readily biodegradable (>70 % within 28 days) based on OECD guidelines (301); Predicted to be readily biodegradable by	30/90 day < T1/2 < 60/180 days in water/ soil or sediment; 10% < DOC removal < 70% based on OECD guidelines (301) 10% < ThOD removal < 60% based on OECD guidelines (301) Inherently biodegradable	T1/2 > 60/180 days in water/ soil or sediment DOC and ThOD removal < 10% based on OECD guidelines Predicted to be recalcitrant by QSAR results.	Not Applicable	No relevant data for classification or substance is considered inorganic and not applicable

[1] Note: The "Purple" category is newly introduced with Version 4.0 to align with the REACH criteria defining vPvBs.

QSAR results	based on OECD guidelines (302, 304A); Predicted to be degradable within weeks to months by QSAR			
Version 4.0 Persistence Hazard Rating Criteria:				
T1/2 < 16[2] days in water, soil or sediment (Still aligns with the GHS aquatic tox approach.) T1/2 < 2 days in air[3] (aligned with REACH) Readily biodegradable (≥70% DOC removal or ≥ 60%ThOD removal within 28 days) based on OECD guidelines (301) Predicted to be readily biodegradable by QSAR results	16 days ≤ T1/2 ≤40 days in fresh or estuarine water 16 days ≤ T1/2 ≤ 60 days in marine water 16 days ≤ T1/2 ≤ 120 days in fresh or estuarine water sediment or soil 16 days ≤ T1/2 ≤ 180 days in marine sediment (upper value aligned with REACH/ECHA P in PBT) 20%[4] < DOC removal < 70% based on OECD guidelines (301) 20% < ThOD removal < 60% based on OECD guidelines (301) Inherently biodegradable based on OECD guidelines (302, 304A); Predicted to be	40 ≤ T1/2 ≤ 60 days in fresh or estuarine water. note: there is no RED value for marine water. See PURPLE value. 120 ≤ T1/2 ≤ 180 days in fresh or estuarine water sediment or soil. Note: there is no RED value for marine sediment. See PURPLE value. (aligned with REACH 'P' definition for PBTs) T1/2 > 2 days in air (aligned with REACH) DOC and ThOD removal < 20% based on OECD guidelines Predicted to be recalcitrant by QSAR	T1/2 > 60 in marine, fresh or estuarine water T1/2 > 180 days in marine, fresh or estuarine water sediment or in soil (aligned with REACH 'vP' definition for vPvBs)	No change

[2] Per GHS 2015 page 460, degradation of >70% within a 28 day period corresponds to a degradation half life of 16 days.
[3] See Page 42 of this https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf page 17 of US EPA P2 Framework Manual 2012 EPA-748-B12-001 https://www.epa.gov/sites/production/files/2015-05/documents/05.pdf Also see Section 3.1 of this (older) document http://www.reach-info.de/dokumente/gutachten_gesamtpersistenz.pdf
[4] See page 38 of this ECHA/REACH doc https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf and OECD, 2005 see page 7, paragraph 35 http://www.oecd.org/chemicalsafety/testing/34898616.pdf

	degradable within weeks to months by QSAR	results.		

2.2 Changes to the Bioaccumulation Endpoint

In order to align the hazard level cut-offs with the ECHA/REACH definitions of persistent, bioaccumulative, and toxic substances (PBTs) and very persistent, very bioaccumulative substances (vPvBs), the bioaccumulation endpoint criteria have been modified as shown in Table 2.

Table 2 - Comparison of Version 3.1 and Version 4.0 hazard rating criteria for the Bioaccumulation endpoint.

GREEN	YELLOW	RED	PURPLE	GREY
Version 3.1 Bioaccumulation Hazard Rating Criteria:				
BCF/BAF < 100 by experimental or QSAR results if log Kow < 6 *or* log Kow < 2 *or* Molecular weight > 1000	100 < BCF/BAF ≤ 500 by experimental or QSAR results if log Kow < 6	BCF/BAF > 500 by experimental or QSAR results if log Kow < 6	Not Applicable	No relevant data for classification. log Kow>2 and no additional information
Version 4.0 Bioaccumulation Hazard Rating Criteria:				
BCF/BAF < 500 by experimental or QSAR results if log Kow < 6 *or* log Kow < 2 *or* Molecular weight > 1000	500 ≤ BCF/BAF ≤ 2000 by experimental or QSAR results if log Kow < 6	2000 < BCF/BAF ≤ 5000 by experimental or QSAR results if log Kow < 6 (aligned with REACH 'B' definition for	BCF/BAF > 5000 by experimental or QSAR results if log Kow < 6. (aligned with REACH 'vP'	No change

(aligned with GHS aquatic tox related values)		PBTs)	definition for vPvBs)	

2.3 New Combined Persistence and Bioaccumulation Hazard Flag

In the revised Material Health Assessment Methodology, Persistence (P) and Bioaccumulation (B) receive a combined hazard flag separate from the combined aquatic toxicity risk flag as detailed in Table 3 below. If the combined PB hazard flag is PURPLE or RED, exposure must be assumed 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.

Table 3 - Deriving the new combined PB hazard flag from Persistence and Bioaccumulation hazard endpoint ratings.

Persistence Hazard Rating	**Bioaccumulation Hazard Rating**	**Combined PB Hazard Flag**
PURPLE	PURPLE	**PURPLE**
PURPLE	RED	**RED**
RED	PURPLE	**RED**
RED	RED	**RED**
Any other combination of hazard ratings may formally be assigned a combined PB hazard flag of 'GREEN' (these combinations factor into the combined aquatic toxicity flag, where they may lead to 'RED', 'YELLOW', or 'GREEN' ratings depending on the aquatic toxicity endpoints).		

2.4 Changes to the Climatic Relevance Endpoint

The rating criteria for the Climatic Relevance endpoint have been changed from a purely list based approach to one that is based on the key metrics that characterize a molecule's climatic impacts. The new rating criteria are in Table 4 below. Note that a GREY rating has been introduced.

Table 4 - Version 4.0 hazard rating criteria for the 'Climatic Relevance' endpoint.

GREEN	YELLOW	RED	GREY
Not listed in Annexes to the Montreal Protocol, ODP = 0 and 100-yr GWP = 0	Not listed in Annexes to the Montreal Protocol, ODP = 0 and 0 < 100-yr GWP[5] ≤ 10 OR Insufficient data to categorize as RED, YELLOW or GREEN based on the Montreal protocol, GWP and ODP, but substance is not a volatile organohalogen. Volatile is defined as boiling point < 260 °C[6]. Organohalogen is any substance containing a fluorine, bromine, chlorine or iodine - carbon bond.[7]	GHS Category 1: Listed in Annexes to the Montreal Protocol. OR ODP > 0 and/or 100-yr GWP > 10	Insufficient data to categorize as RED, YELLOW or GREEN. Note: The Grey hazard rating is only relevant to volatile organohalogens that cannot be categorized as RED, YELLOW or GREEN due to lack of data.

[5] **Regarding pentane, isopentane, and cyclopentane:** Varying GWPs have been indicated from 3 to 11. These substances are *Acceptable* per the US EPA and the EU Commission and are to be assigned a YELLOW hazard rating for this endpoint.
[6] US EPA, Technical Overview of Volatile Organic Compounds, https://www.epa.gov/indoor-air-quality-iaq/technical-overview-volatile-organic-compounds
[7] Note: Fluorinated substances are not ozone depleting substances due to their high stability/lack of reactivity but are often potent greenhouse gases when volatile.

2.5 Changes to the Rules for Assigning Single Chemical Risk Ratings

The rules for assigning Single Chemical Risk ratings in the Version 4.0 Material Health Assessment Methodology are modified as follows (added/modified rules are underlined):

1. If the chemical has received a combined PB hazard flag of PURPLE (see Section 2.3 above regarding the combined PB risk flag), the single chemical risk rating is 'x' and steps 2-6 below do not apply.
2. If the chemical has received a RED risk flag in any of the 17 endpoints resulting from the risk assessment (Section 4 of the Material Health Assessment Methodology regarding the combined Aquatic Toxicity risk flag), the single chemical risk rating is 'x' and steps 3-6 below do not apply.
3. Otherwise, if the chemical has received a GREY risk flag for any endpoint other than Carcinogenicity, Endocrine Disruption, Neurotoxicity, Climatic Relevance, or Terrestrial Toxicity, the single chemical risk rating is 'GREY' and steps 4-6 below do not apply.
4. Otherwise, if the chemical has received any YELLOW risk flags or any GREY risk flags for Carcinogenicity, Endocrine Disruption, Neurotoxicity, Climatic Relevance, or Terrestrial Toxicity, the single chemical risk rating is 'c' and step 5 and 6 below do not apply.
5. Otherwise, if the chemical has received any YELLOW hazard ratings, the single chemical risk rating is 'b' and step 6 below does not apply (the chemical has received only 'GREEN' risk flags, but one or more YELLOW hazard rating).
6. Otherwise, the single chemical risk rating is 'a' (the chemical has received only 'GREEN' hazard ratings).

3 Changes to the Exposure Assessment Methodology

The following changes apply to the Exposure Assessment Methodology.

3.1 Persistence and Bioaccumulation

The following rule has been added to Step 1A of the method:

Substances with a PURPLE hazard rating for the combined PB hazard flag (see Section 2.3 above) 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.

3.2 Assessment of Effluent and Sludge

The Final Manufacturing Stage portion of the Exposure Assessment Methodology has been altered in order to ensure that the fate of individual chemicals potentially entering the effluent are addressed appropriately. (Note that the exceptions in Section 3.1.1 of the Exposure Assessment Methodology still apply as written, i.e., some substances must be x-assessed regardless of exposure considerations). Specifically, the potential for the chemical to volatilize and/or adsorb to sludge, and the ultimate fate of the sludge, must be considered in addition to the presence of the chemical in the effluent itself unless one of the following is true (text in *italics* is taken directly from the Version 3.1 Exposure Assessment Methodology):

1. *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).
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).*
3. *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[8]). 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.[9] 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:

[8] 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.

[9] 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[10] 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 fate of biosolids and digestate in many locations unless identified as hazardous waste per regulatory definitions.

[10] 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

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.[11] In the EU, limits on metals for land application are set by individual member countries.[12] 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".[13]

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.

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.

[11] US EPA, Title 40 Part 305.13

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

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

If testing shows that a chemical is below the required limits within effluent, or present in effluent at or below the incoming concentration[14], 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).[15] 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.[16]
    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 level in which case those must be met.[17] 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):

[14] 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.

[15] 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.

[16] 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

[17] 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.

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 reccomended.

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)[18, 19] using assessment factors defined by the European Commission shall be applied as the effluent limit (see link in footnote below for calculation methods and the Appendix 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 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 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.)

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,

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

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

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.[20] 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)[21] 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 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

[20] 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/

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

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.

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.

4 Changes to the Polymer Assessment Methodology

The following changes apply to the Polymer Assessment Methodology.

Residual monomers and oligomers[22] are now subject to review at 100 ppm or above in the homogeneous materials of the finished product. In the case that a residual monomer is present on the Restricted Substances List, and the threshold indicated there is lower than 100 ppm, or a specific concentration limit (SCL) for any toxicity endpoint of a substance is below 100 ppm as indicated by the Table of Harmonized Entries in Annex VI to the Classification, Labelling, and Packaging of Substances and Mixtures regulation, the lower threshold will apply[23].

The monomer concentration within a molded or extruded plastic part will be assumed to be the same as the monomer concentration within the polymer pellet or resin as purchased from the polymer manufacturer unless testing has shown otherwise.

An exposure assessment may be completed for monomers using the same method as for all other substances within the polymer.

A passed VOC test at the product level may be used as indication that inhalation exposure is not relevant (following the Exposure Assessment Methodology as for other substances).

In addition, any non-biodegradable or non-compostable polymer (see the biodegradability definition for how biodegradability or compostability is determined/verified) that contains an additive that has been intentionally added for the purposes of enhancing degradation renders a product non-certifiable as per the product eligibility requirements stated in Section 2 of the Cradle to Cradle Certified Product Standard, Version 4.0.

5 Changes to the Evaluation of Externally Managed Components (EMCs)

In Version 4.0, the requirements that an externally managed component (EMC) needs to fulfill in order to count as assessed are no longer included in the main standard document. Instead, they are considered a standalone assessment methodology similar to those for geological materials and recycled content materials.

[22] Oligomers are defined as material fraction with molecular weight < 500 Daltons (with reference to https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/polymer-exemption-guidance-manual).
[23] For example, vinyl chloride is on the restricted substances list with a threshold of 5 ppm or 1 ppm depending on application.

5.1 Requirements

In order to count as assessed, an EMC will need to meet all requirements as stated in Section 3.4.1 of the Version 3.1 Cradle to Cradle Certified Product Standard (provided for reference in Section 5.3) with the following clarifications and additions:

- Version 3.1 of the Standard states that: "If, during use of the product for which the EMC is a component, a user is exposed to any part or chemical within the component, or if any part or chemical within the component is released to the environment, the component is not considered an EMC and will be assessed and inventoried like the other materials in the product." The following will be added in the new EMC methodology: 'In addition, any component of the product that is available for exposure to occur (including dermal), such as the housing, any external wiring, etc. may not be considered part of the EMC and must be assessed per the usual methodology.'
- A single core Restricted Substances List (RSL) declaration signed by the applicant or manufacturer of the EMC will be accepted. This declaration must be supported by one or more of the following:
    - RSL declarations from suppliers of all homogeneous materials contained within the EMC (these may be collected by the manufacturer and shared with the assessor; it is not required to provide all declarations to C2CPII)
    - Analytical testing of all internal EMC materials for which no RSL declaration from the material manufacturer has been obtained demonstrating compliance with the RSL. Contact C2CPII for information on appropriate test methods (methods recommended for the Recycled Content Materials Assessment Methodology apply).
    - The EMC manufacturer may sign a declaration if they have sufficient knowledge of the components material and chemical constituents to ensure that all contained materials are RSL compliant.

- The Platinum level Active Cycling requirements will apply to EMCs in determining whether or not an appropriate end of use / take-back system is in place. Specifically, the EMC must meet Platinum level requirements as described in Section 5.9 of the Version 4.0 standard, regardless of the certification level for the product overall.

- If the product is intended to be used outdoors and will be installed in such a way that the housing and/or other components of the EMC will be exposed to environmental media (e.g. rain, soil, ice,), the product must have received an appropriate International Electrotechnical Commission (IEC) International Protection (IP) rating or National Electrical Manufacturers

Association (NEMA) rating[24] (or similar depending on product type and location in which it is sold) for the environment in which it will be used. This will provide some assurance that the unassessed internal components of the EMC will not accidentally be released due to contact with water and soil, etc.

- The applicant will be asked for data on the rate of return for the product itself or for similar product(s) as well as proof that returned EMCs will be handled and recycled in a way that minimizes the risk of human or environmental exposure to hazardous substances. If less than 95% of the EMC is being returned or can be expected to be returned for appropriate handling and recycling (or if data are not available), then landfilling must be assumed as a plausible end of use scenario. In this case, leaching tests are required per the methods described below to ensure that the EMC is not defined as hazardous waste.

- Leaching test requirements for landfill scenario:
    - The extraction method used must be per EN 12457-1 -2 or -3 for granular waste (relevant to the EU's Council Decision 2003/33/EC Waste Acceptance Criteria). Alternatively, if the product will only be sold outside of the EU, then the extraction method outlined in the US EPA's Toxicity Characteristic Leaching Procedure (TCLP) may be employed instead.[25]
    - Eluate must meet the requirements for inert or non-hazardous waste per Section 2.2.2 *Limit values for non-hazardous waste* of Council Decision 2003/33/EC (or most recent version of the clause in the case that the directive is updated or amended) per the requirements in the EU member state(s) where the product is sold.[26] Alternatively, if the product will only be sold outside of the EU then the requirements outlined in the most recent version of the US EPA's TCLP may be met instead.

5.2 Verification

Documentation in support of meeting all requirements listed above will be required. This may include: An RSL declaration, RSL test results, IEC and NEMA rating documentation, hazardous waste test results, data on recovery rates and VOC test results.

[24] Information on IP ratings: https://www.nemaenclosures.com/blog/ingress-protection-ratings/ https://www.cnet.com/how-to/water-dust-resistance-ratings-in-gadgets-explained/
IP and NEMA ratings: http://www.siemon.com/us/standards/nema_comparison.asp

[25] Note: These tests may be used for complex products, but they would have to be granulated prior to completing the tests. See for example: http://sinovoltaics.com/solar-basics/introduction-to-solar-panel-recycling/. Also note that in the EU it is not likely that such a test would ever be needed on a complex electronic product like solar panel because it is mandatory that manufacturers take these back per WEEE.

[26] Limit values are listed for each of three possible liquid to solid (L/S) ratios; refer to extraction method used (either EN 12457-1 -2 or -3) to determine which limit value is relevant.

5.3 Version 3.1 Externally Managed Components (EMCs) Requirements

The following requirements and conditions from Version 3.1 still apply under Version 4.0 (with the modifications and additions described above). The text in *italics* is taken directly from the Version 3.1 Cradle to Cradle Certified® Product Standard, with clarifications and annotations added in parentheses:

The following information must be collected from the applicant or applicant's supplier if a sub-assembly is to be defined as an EMC (see Section 1.3.1.3 for definition and more information on EMCs):

1. *The supplier of the EMC has provided the applicant with a guarantee for take back and appropriate nutrient management. The supplier may designate a third party or parties for implementation.*
2. *The supplier has signed a declaration that chemicals in the EMC will not negatively impact humans or the natural environment during the intended and unintended but highly likely use of the product for which the EMC is a component. This guarantee may be provided if the EMC is Cradle to Cradle CertifiedTM (Gold level or higher), or other appropriate evidence.*
3. *The EMC has undergone testing by an accredited analytical laboratory to* [ensure] *that harmful substances are not being emitted from the EMC above the chemical's analytical detection limits. Off- gas testing is required for all indoor-use EMCs (See Section 3.9 for more information on VOCs emission testing). Migration and leaching testing may be required depending on the type of EMC.*

If the above are completed, the general requirement for full chemical compositional identification and assessment of the EMC will not apply.

The intent of these requirements is for the supplier to indicate, to the best of their knowledge, that the sub-assembly is a sealed component that is manufactured in a way that prohibits the migration of chemicals and materials from the component. If, during use of the product for which the EMC is a component, a user is exposed to any part or chemical within the component, or if any part or chemical within the component is released to the environment, the component is not considered an EMC and will be assessed and inventoried like the other materials in the product. [**Added for Version 4.0**: In addition, any component of the product that is available for exposure to occur (including dermal), such as the housing, any external wiring, etc. may not be considered part of the EMC and must be assessed per the usual methodology.]

It is recognized that it is not possible to know with absolute certainty that chemicals and materials in the EMC will not negatively impact humans or the natural environment during all the possible use and re-use scenarios. The overall intent is to allow for the use of product components that do not need to be

assessed the same way as the rest of a product because they are managed as a whole by the supplier or a third party. The EMC concept was invented by the founders of the Cradle to Cradle® framework to encourage manufacturers to design complex components that are completely managed after their use phase. Examples of potential EMCs are a pneumatic cylinder in an office chair, the motherboard in a computer, the electric motor inside an automated window shade product, and a solar panel.

Required Documentation

The following documents must be submitted to the assessor:

1. *A signed statement from the manufacturer guaranteeing take back and appropriate nutrient management of the EMCs, including a full description of the take back program and how the product or material will be returned.*
2. *A signed declaration that chemicals in the EMC will not negatively impact humans or the natural environment, as detailed above (this guarantee may be provided if the assembly/part is Cradle to Cradle Certified (Gold level or higher), or other appropriate evidence).*
3. *Test results, including a description of the test methods used and laboratory contact information.*

6 Appendix

6.1 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".[27] **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.[28] 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.

[27] Note: The Exposure Assessment Methodology states that, in the case of chemicals released to effluent at the final manufacturing stage facility, if *Persistence* is GREEN for endpoints other than aquatic toxicity, substances with RED or grey hazard ratings released to effluent may receive a YELLOW or GREEN risk rating. The combined aquatic toxicity risk flag is used in the case of the aquatic toxicity endpoint in which case both *Persistence* and *Bioaccumulation* must be GREEN to override a RED aquatic toxicity hazard rating.

[28] http://pubs.rsc.org/en/content/articlehtml/2016/RA/C6RA05406D

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.

6.2 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:

[29] ECHA, Environmental Exposure Assessment, 2016. (See R.16.2 Release assessment). https://echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf

[30] OECD, Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, Revision 1 of the Resource Compendium of PRTR Release Estimation Techniques, January 8, 2013, (See estimation method described on page 25): http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2002)20/rev1&doclanguage=en

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[31]:

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

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.